Where Shall We Begin? Factors to Consider When Developing Psychological Interventions for

Dealing With Stressful Life Events Based on the Results of Three Research Projects

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What we call the beginning is often the end. And to make an end is to make a beginning. The end is where we start from. – T. S. Eliot

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Summary

Over the course of a lifetime, it is almost inevitable to experience stressful events. Many people even experience traumatic events. Nevertheless, what is perceived and appraised as stressful is subjective. This subjectivity should also be reflected in interventions aiming to support and improve coping with stressful and traumatic life events. This refers not only to the design of interventions per se, but also to the conditions under which the interventions are applied. Thus, the aim of the present dissertation is to examine what conclusions can be drawn for the design of future interventions aiming to reduce psychological distress. This is based on the results of three projects on psychological interventions to support coping with psychological distress due to an accident or the COVID-19 pandemic. The results are structured along the transactional stress theory.

Possible implications for the design of future interventions include, for example, clarifying perceptions of a stressor among the target population and other stakeholders prior to the intervention. Furthermore, recruitment interventions should be selected based on the characteristics of the stressor, stressor perceptions, and external circumstances. Assessing and, if possible, addressing participants' pre-existing coping strategies and personal resources can also contribute to the success of an intervention. Further implications are discussed.

Content

1   General Introduction

Life consists of a series of experiences and events. Some of them are positive, some negative, some hardly provoke a second thought while others are perceived as stressful and intense. Most people experience both good and bad normative events such as moving house, changes in school or job, graduations, special celebrations, etc. However, there are also non-normative events. These include, for example, natural disasters, pandemics, war, or accidents. Not all people experience such stressful, sometimes traumatic life events, and not all people react to or evaluate these non-normative events in the same way (Schwarzer & Luszczynska, 2012). What is perceived as stressful is subjective (Fink, 2016), and this subjective evaluation in turn influences both the definition and the handling of stress (Cohen et al., 2016). Correspondingly, interventions on how to deal with stressful events and psychological distress should be guided by a differential assessment of stress as well.

Therefore, the present dissertation considers where, when, and how psychological interventions should be applied to facilitate and improve the management of and coping with non-normative stressful life events. The empirical basis for this is provided by the results of two projects on psychological distress due to an accident and one project on psychological distress due to the COVID-19 pandemic. The empirical findings of the three projects are then examined in relation to theoretical considerations of stress. To this end, the concept of stress and stressful life events are introduced below. This is followed by a brief description of the three projects and the dissertation's aims. Subsequently, the individual scientific publications that have been incorporated into the current dissertation are presented. Finally, findings from these publications are discussed and it is considered how they might inform further research.

1.1 Stress

While the concept of stress is clearly defined in physics, there is no universally accepted definition for *psychological stress*, despite its apparent ubiquity and the large amount of research on the topic (Cooper & Dewe, 2004). Different schools and disciplines have shaped different approaches to stress. In the following, stress is briefly examined as (1) a response, (2) a stimulus, and (3) a cognitive-transactional process.

1.1.1 Stress from a Response-based Perspective

As the term suggests, the *response-based perspective* sees stress as a response to an adverse situation. To this end, the distinction between the trigger or stimulus, called the *stressor*, and the reaction to it, called the *stress response*, was introduced by Hans Selye (Fink, 2016; Selye, 1936). According to Selye, an organism typically goes through three stages when reacting to a stressor (Selye, 1956). First, an *alarm reaction* is triggered whereby the organism prepares itself for a so-called 'fight-or-flight response' by activating the sympathetic nervous system. 'Stress has been called both the spice of life and the kiss of death' (Cooper & Campbell Quick, 2017, p. 1). This quote illustrates that stress can be both beneficial and detrimental. While a little stress over a short period of time can increase alertness and performance, too much stress that lasts too long can have negative consequences (Bienertova-Vasku et al., 2020). Namely, if a stressor cannot be resolved with the alarm reaction, the organism moves to the second stage of the stress reaction called the *resistance stage*. The resistance stage is characterized by the organism's more or less successful adaptation to the stressor and requires a lot of resources. When the stressed organism's resources for adaption are depleted, it reaches the third stage of the stress reaction, the *exhaustion stage*. The parasympathetic nervous system is activated. If the organism cannot recover, a breakdown is likely to occur (Schwarzer & Luszczynska, 2012).

The response-based perspective is still dominant in biomedical sciences. However, the perspective mainly focuses on the stress response, neglecting the fact that different stressors do not necessarily have to lead to the same response (Koolhaas et al., 2011).

1.1.2 Stress from a Stimulus-based Perspective

The differential impact that varying stressors can have on the stress reaction is taken into consideration in the *stimulus-based perspective* of psychological stress. According to this perspective, different stimuli can trigger different reactions. Yet, it is also assumed that the same stimulus causes the same reaction strength in all individuals. The advantage of this assumption is that an objective measurement of stress would be possible (Lazarus, 1999). However, this approach is often criticized for neglecting individual factors such as personality, resources, and personal interpretations, which arguably have an impact on the evaluation of a stressor (Cohen et al., 2007; Koolhaas et al., 2011; Schwarzer & Luszczynska, 2012).

1.1.3 Stress from a Cognitive-transactional Perspective

The varying influences of both the stressor and the stress response are taken into account when stress is viewed from the *perspective of a cognitive-transactional process*. The *transactional theory* assumes an interaction between the characteristics of the stressor, and the individual, their abilities, and resources (Lazarus, 1999; Lazarus & Folkman, 1984, 1987). Stress management is seen as a dynamic and highly individual process occurring in continuous and reciprocal, i.e., transactional, interaction between the individual and their environment (Bengel & Hubert, 2010; Lazarus & Folkman, 1984). The stress process is started only when a person actually notices an external or internal change occurring. If a change is perceived, it becomes a potential stressor. Then two successive *appraisal processes* are initiated. First, with the *primary appraisal*, an assessment is made of whether the potential stressor and its possible consequences, are relevant to a person's physical,

psychological, and social well-being, as well as whether action is needed to maintain or to restore that well-being. In case the potential stressor and its possible consequences are evaluated as neutral, irrelevant, or pleasant, no adaption effort is required and consequently, no stress arises. However, if the evaluation determines that the potential stressor and its consequences may be harmful, threatening, or challenging, then an adaption is indicated. The type and extent of adaptation are determined by means of the *secondary appraisal*. The purpose of the secondary appraisal is to examine what resources and strategies for coping with the potential stressor a person has, and how they assess the relation between adaptation requirements and their resources. If the relation between adaptation requirements and personal resources is assessed as balanced, no stress arises. If, on the other hand, the relation between resources and adaptation requirements is assessed as unbalanced, the person experiences stress in the form of emotional and physiological reactions. This stress experience in turn triggers *coping behavior*. Coping describes 'constantly changing cognitive and behavioral efforts to manage specific external and internal demands that are appraised as taxing or exceeding the resources of the person', i.e., that are appraised as stressful (Lazarus & Folkman, 1984, p. 141). It can be *problem-focused* when aiming to deal with the stressor itself, or *emotion-focused* when aiming to regulate the emotions caused by the stressful situation. There are different subtypes of both forms of coping (Biggs et al., 2017; Faltermaier, 2017).

Depending on the results of the applied coping, a reappraisal can occur, whereby the stressful situation is reassessed. If one is satisfied with the result of the coping and one's reaction, learning and maturation can occur, which in turn can influence future appraisals (Bengel & Hubert, 2010; Lazarus, 1999, 2006; Lazarus & Folkman, 1984). In the context of this transactional theory of stress, Lazarus and Folkman came to define stress as 'a

relationship with the environment that a person appraises as significant for his or her well-being and in which the demands tax or exceed available coping resources' (1986, p. 63).

Figure 1

Model of the transactional theory of stress by Lazarus and Folkman (1984)

(Potential) Stressor
Internal (person) and external (environment) demands

Primary Appraisal:
• Are the (potential) stressor and its consequences relevant to one's well-being?
• Is adaption necessary to maintain or restore that well-being?

Potential stressor appraised as irrelevant	Potential stressor appraised as pleasant	Potential stressor appraised as harmful	Potential stressor appraised as threatening	Potential stressor appraised as challenging
No adaption effort needed	**Situation assessed as stressful**			
	Adaption effort needed			

Secondary Appraisal:
• What resources and strategies for coping with the stressor are available?
• Is the relation between resources and adaptation requirements balanced?

Balanced relation between resources and adaptation requirements	**Unbalanced relation between resources and adaptation requirements**

No physiological or emotional reactions: no experience of stress	**Physiological and emotional reaction: experience of stress**
	Coping behavior (Emotion-Focused or Behavor-Focused)

Satisfied	**Not satisfied**
Learning and Maturation	

1.2 Stressful Life Events

While according to the transactional theory of stress it is purely subjective what is and is not a stressor, different types of stressors can nevertheless be distinguished. For this purpose, criteria such as the controllability, predictability or duration of the stressor and its consequences can be used for the characterization of stressor categories (Knoll et al., 2017; Renneberg et al., 2009). When looking at another criterion, the severity of a stressful life event, the three categories *daily hassles*, *critical life events* and *traumatic events* can be distinguished (Kanner et al., 1981; Knoll et al., 2017; Renneberg et al., 2009).

Of these three categories, daily hassles tend to be the least severe (Renneberg et al., 2009). Lazarus defined daily hassles as 'experiences and conditions of daily living that have been appraised as salient or harmful or threatening to the endorser's well-being' (Lazarus, 1984, p. 376). They are minor everyday inconveniences and annoyances. Although they trigger little stress per se, they tend to occur frequently and regularly and can thus accumulate. As a result, such micro stressors of everyday life can become chronic burdens and affect health and well-being (Graf et al., 2017; Larsson et al., 2016; Lazarus, 1984; Udayar et al., 2021).

Critical life events refer to spatially and temporally clearly definable and limited 'interruptions in the flow of life' (Bengel & Hubert, 2010, p. 29) that are subjectively perceived as stressful. This includes events that are bound to happen or to be expected over the course of a person's life, i.e., they are normative. However, these events can be positive or negative and, depending on the circumstances, sudden or expected (Bengel & Hubert, 2010). Examples include a school transition or graduation, retirement, a vacation, a separation or divorce. The non-occurrence or absence of an event, such as an unfulfilled desire to have children, can constitute a critical life event as well. Since such occurrences or non-occurrences are often associated with a change of life situation and circumstances, they

require a high level of adjustment from those affected. (Aymanns & Filipp, 2018; Renneberg et al., 2009).

The most severe category of stressors are traumatic events, i.e., non-normative events in which a person is exposed to actual or threatened death, serious physical injury, or sexual violence. This may occur through (1) direct exposure, (2) witnessing the trauma, (3) learning that a relative or close friend has been exposed to trauma, or (4) indirect exposure to aversive details of the trauma, usually in the context of professional duties (American Psychiatric Association APA, 2013; Kapfhammer, 2014). Traumatic events can be classified based on several categories: They can be accidental (e.g., natural disasters and accidents) or man-made (e.g., war and rape). They can be brief and occur once (Type-I trauma) or last longer and occur repeatedly (Type-II trauma). Another category are medically induced traumas. They are defined as medical situations that involve a sudden catastrophic event, such as waking up during surgery (Maercker, 2019). Traumatic events often overwhelm, render helplessness, and cause fear. Accordingly, the experience of a traumatic event can be a trigger for psychological distress and disorders including anxiety and depressive disorders, *post-traumatic stress disorder* (PTSD) and *adjustment disorder* (AjD) (Frommberger et al., 2014; Galatzer-Levy et al., 2018; Renneberg et al., 2009). Findings from the World Mental Health Survey Initiative, which collected data from 24 countries worldwide, show that over half of all respondent-reported cases of traumatic experiences were covered by the following 5 traumatic events: (1) witnessing death or serious injury, (2) the unexpected death of a loved one, (3) being mugged, (4) being in a life-threatening vehicle accident, and (5) experiencing a life-threatening illness or injury (Benjet et al., 2016; Kessler et al., 2017). The study also showed that 70.4% of all participants had experienced a traumatic event with 30.5% of participants stating that they had experienced four or more traumatic events (Benjet et al., 2016). Although traumatic events are considered non-normative events that not all people

experience during their lives, these figures show that they are more common than assumed (Ashby et al., 2021; Ogle et al., 2013). Despite the high reported prevalence for experiencing traumatic events, only a comparatively small portion of those affected develop psychological problems such as PTSD or AjD (Aymanns & Filipp, 2018; Knipscheer et al., 2020; Renneberg et al., 2009). The present dissertation takes a closer look at two traumatic events: experiencing an accident and the COVID-19 pandemic, and their potential psychological sequelae.

1.2.1   Accidents

An accident can be defined as 'a sudden, unintentional harmful effect of an unusual external factor on the human body that results in impairment of physical, mental and psychological health or death' (Egli, 2018). This definition includes all forms of leisure and work-related accidents. Another characteristic of accidents is that they happen suddenly, are unpredictable and uncontrollable. Consequently, they can not only pose a threat to one' s life, integrity, and health, but also have a high potential for traumatization (Angenendt, 2014, 2021).

As previously described, accidents are among the most common potentially traumatizing events. Since 2013, more than 800,000 accidents have been recorded annually in Switzerland alone (Koordinationsgruppe für die Statistik der Unfallversorgung UVG, 2021). In terms of Switzerland's population of approximately 8.7 million people (Bundesamt für Statistik, 2021), this corresponds to an annual prevalence of almost 10%. However, these accident statistics must be viewed with caution, as they do not consider people who are not insured under the accident insurance law in effect in Switzerland. This concerns children, persons in training, homemakers as well as pensioners, provided they are not gainfully employed, and altogether accounts for nearly half of the population (Koordinationsgruppe für die Statistik der Unfallversorgung UVG, 2021). It can therefore be assumed that the actual

number of accidents is even higher. Accidents occur not only frequently, but also generate high costs. In 2018, approximately 4.9 billion Swiss Francs were spent on accident-related insurance benefits from accidents that were newly registered in 2018 and from accidents that occurred in previous years but still generated costs in 2018. In addition to acute healing and care costs, this also includes rehabilitation costs, per diem sickness benefits and disability pensions (Koordinationsgruppe für die Statistik der Unfallversorgung UVG, 2021). However, it is important to take into account that accidents can also result in other types of costs, such as psychological distress, reduced social functioning and a general loss of quality of life, which often are not or cannot be directly recorded (Abegglen, 2017).

Psychological distress due to an accident can begin with acute stress and shock immediately after the accident. In this context, individual stress symptoms can be regarded as 'the human psyche's normal reaction to an abnormal situation' that is not per se pathological (Angenendt, 2014, p. 666). Most accident victims successfully adjust to the accident within a few days or weeks, and the acute stress reaction subsides (Angenendt, 2014; Bengel et al., 2019; Bengel & Hubert, 2010). However, for a significant minority, the stress symptoms persist. In these cases, the adaptation effort fails, and specific stress-related disorders may develop (Maercker, 2019). The most common specific stress-related disorders after an accident include PTSD, AjD, anxiety and depressive disorders, and somatoform pain disorders (Angenendt, 2014; Frommberger et al., 2014).

Not recognizing and/or treating psychological distress after an accident can have far-reaching consequences. The original symptoms may progress or become chronic, and the healing process may become more complex. In a study on psychological sequelae of traumatic injury, Bryant et al. (2010) found that 31% of their participants had a psychiatric diagnosis one year after their injury. The most common diagnoses were depressive disorder, generalized anxiety disorder, PTSD and agoraphobia (Bryant et al., 2010). Munter et al.

(2020) found a lower prevalence: One year after experiencing a traumatic injury, about 7% of

participants showed clinically significant anxiety symptoms and another 7% of participants

showed clinically significant depressive symptoms. In a study by O'Donnell et al. (2016)

28% of the participants who were severely injured after experiencing a Type-I trauma still

met the criteria for at least one psychiatric diagnosis even six years later, and of those people,

45% showed comorbid disorders. These findings suggest a chronification of the initial

psychological stress symptoms and thereby a complex rehabilitation process.

Psychological distress and disorders after accidents can also have an impact on work

life. Various studies have shown that lower psychological well-being and the presence of a

psychological disorder can complicate and delay return to work (e.g., Kellezi et al., 2017;

Kendrick et al., 2017; Matthews et al., 2009; Matthews & Chinnery, 2005).

After an accident, the focus of treatment often justifiably lies on the physical injuries.

However, even in the further course of treatment psychological distress often remains

unnoticed – despite the various findings on long-lasting consequences and complaints. In

those cases where psychological distress is recognized, the situation is often aggravated by

the fact that there are not enough therapy and support options available, which can result in

long waiting times. It is also often unclear who is to pay for treatment costs, which further

complicates the treatment of psychological distress (Angenendt, 2014, 2021; Angenendt et

al., 2016). Currently, the long waiting times are largely due to the second stressor considered

in this dissertation, the COVID-19 pandemic and its consequences.

1.2.2 The COVID-19 Pandemic

Since the first cases of a pneumonia of unknown origin were reported in Wuhan,

China, in December 2019, this disease caused by the coronavirus strain SARS-CoV-2 virus,

or COVID-19 for short, has been keeping the world at bay. By the time the World Health

Organization (WHO) declared the COVID-19 outbreak a pandemic in March 2020, the

highly contagious virus had already spread to all parts of the world (Benfante et al., 2020; Liang et al., 2020). From March 2020 until the date of submission of this dissertation in January 2022, more than 335 million infections and 5.5 million deaths from COVID-19 have been reported (Ritchie et al., 2022).

The COVID-19 pandemic not only affects the physical well-being but has a profound impact on all aspects of life and society (Horesh & Brown, 2020; Sanchez-Gomez et al., 2021). Pandemic-related stressors such as social distancing, isolation, fear of contagion and health consequences, worries about and grief at the loss of loved ones, unemployment and financial worries can cause stress and negatively impact mental health (Brooks et al., 2020; Fiorillo & Gorwood, 2020; Holmes et al., 2020; Kira et al., 2020; Sritharan & Sritharan, 2020).

A growing body of research addresses mental health outcomes due to and surrounding the COVID-19 pandemic. By now, numerous studies from all over the world report a significant increase in stress, anxiety and depressive symptoms - both in the general population (e.g., de Quervain et al., 2021; Ettman et al., 2020) and in special groups such as health care workers (e.g., Benfante et al., 2020; Luo et al., 2020) or persons with pre-existing psychological disorders (e.g., Gobbi et al., 2020; Murphy et al., 2021). Current data from a Swiss survey on the psychological consequences of the COVID-19 pandemic present similar findings (de Quervain et al., 2021). In addition, an increase in substance use is reported among about half of the individuals who were using prescription medications, nicotine, or illegal drugs prior to the pandemic in the Swiss study (de Quervain et al., 2021). Similar results about an increase in substance abuse among individuals who were already using prescription medications or drugs prior to the COVID-19 pandemic (Boehnke et al., 2021), as well as decreased sleep quality in the general population (Didriksen et al., 2021; Varma et al., 2021) were reported in studies from other countries as well.

The experience of some pandemic-related stressors, such as losing one's job, can be considered a critical life event. Other stressors, such as contracting COVID-19 that threatened one's own life or witnessing the death of a close person, even qualify as traumatic events. Therefore, it is not surprising that several studies have reported an increase in the prevalence of PTSD symptoms since the onset of the COVID-19 pandemic (e.g., Liang et al., 2020). However, not only individuals who were themselves threatened by COVID-19 (direct exposure) or who lost someone close to them (indirect exposure) report PTSD symptoms (Bridgland et al., 2021; Cooke et al., 2020). Thus, some researchers argue that the Covid-19 pandemic's main cause of traumatization is indirect exposure. However, this does not occur primarily in the line of duty, as the definition criteria of a traumatic event state (American Psychiatric Association, 2013). Instead, the repeated and ongoing exposure, e.g., through media reports or prolonged protective measures by governments, as well as the perception of future trauma, are considered to be the main reasons that make the COVID-19 pandemic a traumatic event (Bridgland et al., 2021; Cooke et al., 2020; Kira et al., 2020). While repeated exposure theoretically meets the current criteria of a traumatic event (APA, 2013), imagining possible future events does not. There are, however, at least two reasons why imagining future trauma could qualify as exposure to a traumatic event. First, there is research showing that the anticipation of a potentially traumatic event can trigger PTSD-related symptoms and distress at similar or even higher levels than past trauma (Bridgland et al., 2021). This has been shown, for example, with soldiers who were about to be deployed (Berntsen & Rubin, 2015), and with pregnant women when anticipating childbirth (Goutaudier et al., 2018). Second, a growing body of research suggests that remembering past events and imagining future events engage similar neuronal systems and functions (Addis, 2020; Buckner & Carroll, 2007; Schacter et al., 2012). Therefore, Addis (2020) argues, that remembering and imagining essentially depend on the same process. Accordingly, the COVID-19 pandemic

and its consequences can become a traumatic event not only through direct or indirect exposure, but also through repeated mental preoccupation with it. Because of this multifaceted exposure, the still prevailing virus and disease, and the many associated measures and consequences, the COVID-19 pandemic further comprises a traumatic event that creates a high demand for psychological support worldwide.

1.3 Interventions to Reduce Psychological Stress

While most people can handle a certain amount of stress, or rather certain stressors, well on their own, stressors such as traumatic events simply overwhelm many people and exceed their stress handling capacity (Galatzer-Levy et al., 2018; Renneberg et al., 2009). Based on the considerations outlined above, both the COVID-19 pandemic and the experience of an accident represent such traumatic events that generate the need for psychological support and interventions. In this context, the question arises as to which interventions are best suited when and for whom. To answer this question, the results of three different projects, all with the goal to reduce psychological distress due to a traumatic event, are discussed. To describe the projects, the following four criteria are used: (1) the theoretical background and topic, (2) the aims, (3) the scope and (4) the mode of delivery, i.e., whether the intervention is delivered face-to-face or internet-based. Since two of the three projects include an internet-based intervention, however, these will be described in more detail before the projects are outlined.

1.3.1 Internet-Based Interventions

Internet interventions include all psychosocial services 'that use the Internet as a medium to help people cope with psychological symptoms and to counteract them' (Berger et al., 2020, p. 677). Different forms of IBI can be classified, for example, according to the degree of automation and locality (Berger et al., 2020).

In terms of automation, a distinction can be made as to whether an intervention is conducted by a healthcare professional or whether it runs automated. The spectrum ranges from completely automated interventions without any contact with a healthcare professional to personally delivered interventions in which the internet serves only as a communication channel. These personally delivered interventions, which usually take place via chat, e-mail or video calls, come closest to traditional therapy, which takes place on-site and face-to-face (Berger et al., 2020; Berger & Krieger, 2018). The amount of effort that the healthcare professional must provide is also comparable to traditional therapy. IBI in which the internet serves not only as a communication channel but also as an information medium are often referred to as *internet-based self-help* (Berger, 2015). Internet-based self-help interventions usually comprise different modules, which include psychoeducational information and therapeutic exercises, and are completed within a given time frame (Berger et al., 2019). Internet-based self-help interventions can be divided into interventions with planned contact (guided), and without contact (unguided) with a healthcare professional. The contact with a healthcare professional in guided interventions can be more or less intensive (Berger, 2015; Berger et al., 2020). A mixed form regarding contact with a healthcare professional is represented by interventions with guidance-on-demand. Thereby, contact with a healthcare professional is established on demand, but not per se scheduled or planned (Baumeister et al., 2014; Berger et al., 2011; Rheker et al., 2015).

The second dimension, locality, can be used to determine the extent to which an intervention is delivered remotely or on-site. There are interventions that take place entirely remotely, and there are blended interventions, in which online and on-site elements can be combined in different ways (Andersson, 2016, 2018; Berger et al., 2020; Erbe et al., 2017).

IBI offer several advantages. The online format allows for a lot of geographical flexibility. The interventions can be used from anywhere, allowing people who live isolated

or remotely, or who are not particularly mobile, to apply them. In addition, the more automated the internet-based intervention is, the greater the associated temporal flexibility. A completely automated intervention can be used at any time, independent of office hours or appointment schedules (Berger, 2015; Ebert et al., 2015). The temporal flexibility also allows for individual and learning pace, and, as materials can be viewed at any time and multiple times, for deeper reflection (Berger, 2015; Spek et al., 2007). Self-reflection and a sense of self-determination about the content can also be deepened by the need to write down, rather than (just) express orally, one's own thoughts and reflections in some IBI. Furthermore, the absence of physical contact can reduce the fear of stigmatization. In addition, the inhibition threshold to seek help and to be open and honest may be lower when compared to face-to-face interventions, as IBI often take place in a relatively anonymous setting (Berger, 2015; Ebert et al., 2014, 2016a). Another advantage is the relatively easy scalability (Berger et al., 2020). Once the intervention is created, it can be multiplied all the more easily the higher the degree of automation. Especially in the case of internet-based self-help interventions, this can save a lot of financial and human resources (Berger et al., 2020; Bradley et al., 2012; Wilson & Zandberg, 2012; Zamboni et al., 2019). Unguided interventions in particular are often comparatively easily accessible and low-threshold, since interested persons can usually register themselves (Ebert et al., 2014, 2016a, 2016b).

However, IBI also involve some disadvantages. For example, the ease of access, the high degree of flexibility in terms of time and space, as well as the lack of face-to-face contact can lead to lower commitment. Furthermore, the lack of personal contact makes it almost impossible to be able to respond appropriately in crisis situations. In addition, in IBI without visual or auditory contact, the non-verbal and/or para-verbal exchange may be missing. Another disadvantage of IBI are dubious offers, which are sometimes difficult to recognize but can be easily spread (Berger, 2015; Berger et al., 2011; Mira et al., 2019). This

also points to another disadvantage: in order to use IBI, one needs certain skills, such as computer skills, reading and writing skills or the health literacy required to be able to select suitable and serious offers (Berger & Caspar, 2011; Perestelo-Perez et al., 2020).

These advantages and disadvantages do not apply equally to all forms of IBI. Whereas unguided self-help interventions are relatively inexpensive, easily scalable, and flexible to use, there are usually no or only limited possibilities to adapt them to individual user needs. In contrast, individualizing treatment is easier with chat or video therapies, but time flexibility is limited in such interventions because healthcare professionals must be available and the interventions take a similar amount of time as face-to-face interventions (Berger, 2015; Berger & Caspar, 2011). This brings about a connection to the topic of this dissertation: given the advantages and disadvantages of particular modes of intervention, it seems important to consider which mode of intervention and which form of that mode, e.g., which type of IBI, is likely to be most appropriate and effective for a particular topic and targeted population when planning an intervention.

Research on IBI has not only increased significantly in recent years but has also shown them to be an effective form of treatment for many different psychological problems and disorders (e.g., Andersson et al., 2014; Andrews et al., 2010; Spek et al., 2007; Wilson & Zandberg, 2012) . However, both the research on and the supply of IBI has been further boosted due to the COVID-19 pandemic, since the pandemic caused a large increase in the demand for psychological support (Luo et al., 2020). Yet, the capacity of available (traditional) face-to-face treatment is limited, which has led to long waiting times in many places where help could be provided. IBIs can help remedy this situation. Since they do not require face-to-face contact, IBIs can readily meet the pandemic-related demand for social distancing and provide both an effective alternative to face-to-face therapy and an interim offer until a therapy slot becomes available (Halder, 2020; Luo et al., 2020; Wind et al.,

2020). To address this, many new programs are specifically designed to help cope with the COVID-19 pandemic, its consequences, and resulting stress (e.g., Al-Alawi et al., 2021; Soklaridis et al., 2020; Sotoudeh et al., 2020; Wahlund et al., 2020). This was also the goal of the *ROCO project*, which is part of this dissertation and described in the next chapter.

1.4 Empirical Background: The OptiFAB, SelFIT and ROCO Projects

Since the interventions are described in detail within the scientific articles integrated in this dissertation, the description in this section is kept short and is structured according to the previously mentioned criteria (i.e., theoretical background and topic, aims, scope and mode of delivery).

1.4.1 OptiFAB

Background and topic. The acronym *OptiFAB* stands for 'Optimization of the Work and Health Questionnaire' (German: Optimierung des Fragebogens Arbeit und Befinden). The project was conducted in collaboration with the Swiss National Insurance Fund (Suva) between 2010 and 2015. More specifically, a randomized controlled trial (RCT) was carried out in the Suva agencies in Bern and Zurich. The two articles about the OptiFAB project included in the present dissertation are based on the data collected at the agency in Bern.

The OptiFAB project is based on the results of a predecessor study *EBEBS* (German: Erkennung und Behandlung psychischer Störungen im Rahmen von Unfallfolgen und beruflichen Erkrankungen; Siegenthaler, 2011) on the recognition and treatment of mental disorders in the context of accidents and occupational diseases. Accidents are not only frequent and cause high costs, but these costs are also highly skewed, in that a few cases account for most of the costs (Koordinationsgruppe für die Statistik der Unfallversorgung UVG, 2021). However, a significant number of people who are objectively not seriously injured are often found among the cost- and resource-intensive cases (Elmiger, 2015). In line with the subjective assessment of a stressor according to the transactional stress theory

(Lazarus & Folkman, 1984), subjective well-being should therefore also be included if potential psychological complaints and resulting complex rehabilitation processes are to be identified. To implement the goal of being able to recognize complicated rehabilitation processes at an early stage, the Work and Health Questionnaire (WHQ, German: FAB; Abegglen et al., 2017a) was developed and evaluated in the EBEBS project. In this questionnaire, the personal well-being and the assessment of the work situation are evaluated from the perspective of the injured person. Thus, the questionnaire provides an early and systematic self-assessment of subjective stress and well-being.

Aims and Scope. The use and implementation of the WHQ was to be optimized in the OptiFAB project. More specifically, the WHQ should be conducted by the case managers of the Suva agency in Bern as a screening tool for all claimants who have had an accident up to three months before. Based on the results of the WHQ, an in-depth diagnostic assessment of individuals with an increased risk of a complicated rehabilitation process was carried out. Within a stepped care approach, as used by Suva, an in-depth diagnostic is necessary to assess the appropriate intensity of treatment and to adapt the supportive measures more precisely to the needs of the injured person. Based on the results of the diagnostic, specific occupational and mental health counselling interventions were developed, applied and assessed (Abegglen, 2017; Abegglen et al., 2017a).

Mode of Delivery. The intervention was implemented face-to-face. Suva claimants who showed increased work-related stress in the WHQ received a work-related coaching and a structured observation of the workplace environment. This was conducted by consultants and coaches from a private company specializing in coaching and human resource management (cpmo, 2015). Suva claimants who showed increased psychological stress in the WHQ received mental health coaching, which took place at the Psychiatric Outpatient Clinic of the Institute of Psychology of the University of Bern. Suva claimants who showed

increased work-related as well as mental stress in the WHQ received both. This means that the OptiFAB intervention was highly oriented towards the needs of the individual participants, i.e., it was tailored (Gagliardi, 2011).

1.4.2   SelFIT

Background and topic. The *SelFIT project* was a follow-up project to the OptiFAB project. It was conducted from 2018 to 2022 in partial cooperation with Suva and also consisted of an RCT. SelFIT stands for 'Fit again after an accident' (German: Selber wieder fit nach einem Unfall).

SelFIT was also about the psychological well-being of people who have suffered an accident. The idea was to prevent injured persons from developing psychological distress in the first place. Thus, the first of the three projects, EBEBS, aimed at the early detection of psychological distress and the ensuing risk for a complicated rehabilitation processes by means of the WHQ. The second project, OptiFAB, was about developing, executing, and evaluating a tailored face-to-face intervention based on the results of a screening with the WHQ and a subsequent diagnostic. The goal of the third project, SelFIT, was to develop an easily and quickly accessible intervention for people who had experienced an accident. After an accident, the focus of treatment is mostly on physical problems. Due to this, people who suffered an accident often realize only after the end of their medical treatment or rehabilitation that that they cannot cope well with the consequences of their accident in everyday life. This can lead to stress and stress-related disorders such as AjD. The idea behind SelFIT was to prevent this.

Aims and Scope. The intervention was therefore oriented towards the treatment of AjD. However, since no diagnosed AjD had to be present to be allowed to participate in the intervention and no diagnostic assessment was conducted prior to participation, the intervention was designed to support *adjustment problems*. For this purpose, various

techniques of Cognitive Behavioral Therapy (CBT), but also mindfulness and acceptance-facilitating elements were included in SelFIT. The aim was to evaluate the efficacy and cost-effectiveness of the newly developed program SelFIT for people with adjustment problems after having experienced an accident.

Mode of Delivery. Since the intervention was intended to be accessible as easily and quickly as possible, SelFIT was designed as a low-threshold unguided internet-based self-help intervention. The intervention consisted of eight thematic modules, an introduction and a conclusion, and lasted a total of twelve weeks.

1.4.3 ROCO

Background and topic. The ROCO project was launched in April 2020 in response to the onset of the COVID-19 pandemic. The results of early studies from China, where the pandemic started, suggested that not only the pandemic and its health consequences, but also pandemic-related safety measures such as social distancing, the obligation to work from home, and lockdowns could have an impact on mental health (Qiu et al., 2020; Wang et al., 2020; Yao et al., 2020). Similar pandemic-related safety measures have been implemented in Switzerland (Bundesamt für Gesundheit BAG [Federal Office of Public Health FOPH], 2021).

Aims and Scope. To prevent COVID-19 related psychological distress, or to offer easily accessible psychological help in case of already existing COVID-19 related psychological distress, the ROCO project was created. ROCO stands for 'Resilience and Optimism during COVID-19'. While the subject is different, ROCO is based on the SelFIT intervention, which was adapted by the addition of COVID-19-oriented elements. Therefore, the theoretical orientation of the ROCO program is similar to that of SelFIT.

Mode of Delivery. ROCO was implemented as a brief, internet-based self-help intervention for several reasons. First, at the time of the intervention development, it was

likely that psychological help could not be provided face-to-face due to the quarantine measures. Furthermore, the intervention should be easily accessible and available as quickly as possible. Finally, due to an increasing demand for psychological support, the choice of the internet-based mode was also intended to take a possible staff shortage into account. The intervention comprised six modules and lasted a total of three weeks.

1.5 Aims of This Dissertation

It is one of the goals of both health psychology and clinical psychology to support human health. While clinical psychology focuses more on psychological problems and disorders, health psychology is primarily concerned with physical health (Knoll et al., 2017). Regardless of the specific focus, both disciplines need effective interventions as well as an understanding of the conditions under which these interventions can best be used to support and promote human health (Faltermaier, 2017; Grawe, 2004; Kraemer et al., 2002). The aim of this dissertation is the investigation of such optimal conditions. More specifically, it is examined what conclusions can be drawn for the design of future interventions aiming to reduce psychological distress based on the results as well as the similarities and differences of the three projects described above.

Differences between the projects include, for example, the two different critical events, accidents and the COVID-19 pandemic, that were addressed. Furthermore, one intervention was implemented face-to-face, the others internet-based. While the face-to-face intervention involved personal contact, the other two were unguided self-help interventions. The scope and duration also differed. Similarities include that all three interventions are concerned with a traumatic event and that they all aim to support the successful adaptation to the respective traumatic event and thus, in essence, to reduce psychological stress.

These similarities and differences bear various references to the transactional stress theory (Lazarus & Folkman, 1984): Coping with different stressors, which in this case can be

appraised as traumatic events, can be supported differently, with the goal being the avoidance or reduction of stress. Due to these references, the model was used as a framework against which the findings of the scientific articles included in this dissertation are analyzed and discussed. Potential implications for the design of interventions are also organized based on the elements of the theory.

Of the six scientific articles included in the following chapter, the first two articles refer to the OptiFAB project. Article 1 describes the main outcomes, and the second article describes the results of an exploratory moderator analysis. The third article is the study protocol of the SelFIT project. Articles 4 to 6 are the study protocol, the main outcomes, and the results of a predictor analysis of the ROCO intervention. The articles are all presented in their final versions submitted to the respective journals and therefore not all formatted according to APA standards.

2   Submitted Scientific Articles

2.1 Article 1: Effects of a tailored multidisciplinary counselling intervention to support the adjustment process after a traumatic injury: a randomized controlled trial

Effects of a Tailored Multidisciplinary Counselling Intervention to Support the Adjustment Process After a Traumatic Injury: A Randomized Controlled Trial

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Abstract

Purpose: To investigate the efficacy of a tailored counselling intervention for injured workers regarding different aspects of subjective well-being.

Materials and Methods: Prospective randomized controlled trial with 192 mildly-to-moderately injured workers who were on sick leave for at least 18 weeks and showed a high-risk profile for a complicated rehabilitation process in a screening. Patients were assessed at baseline, 12 and 18 months post-injury. The outcome variables concerned five aspects of subjective well-being (negative feelings, life and job satisfaction, satisfaction related to family and health). Both the control and the experimental group received conventional case management. Participants in the intervention group additionally received tailored workplace interventions and/or mental health counselling sessions.

Results: Participants in the intervention group received an average of 2.23 ($SD = 6.94$) counselling sessions. Both groups showed a significant reduction (mean (95% CI) of negative feelings control group 2.6 (2.3 to 3.4), intervention group 2.4 (1.6 to 3.4)), with a significant difference in negative feelings between the groups ($p = 0.01$).

Conclusions: Our results suggest that a tailored counselling intervention has a modest long-term effect ($d = .74$) on negative feelings for mildly-to-moderately injured workers. However, future studies should evaluate the feasibility of this study's treatment approach.

Introduction

According to Swiss law and the Swiss National Insurance Fund (Suva) an accident is defined as a sudden, unintentional harmful impact of an unusual external factor on the human body that results in impairment of physical, mental, and psychological health. This definition includes all forms of work-related and recreational accidents, but is to be distinguished from illness or other forms of injury [1,2]. Many people who suffer an accident recover quickly. However, more complicated recovery processes including psychosocial problems, emotional distress and long-time sick leaves are common even in cases of mild-to-moderate injuries [3,4]. Kendrick et al. [3] found that most injured people reported clinically relevant reductions in health-related quality of life up to 12 months after the injury. Additionally, a significant proportion of psychological problems were reported for this population, especially for the early recovery phase [3]. In a study by Bryant et al. [5] similar results were found: almost one third of all participants showed a psychiatric diagnosis one year after the accident.

Several studies have shown that early psychological counselling interventions can significantly alter this pattern [6-8]. Moreover, psychological counselling has proven to be effective in supporting adjustment processes to a wide range of adversities [9-11]. Thus, the provision of counselling constitutes an important means of intervention for vulnerable injured persons. Yet, both people with psychological distress and injured people often receive only fragmented care and are insufficiently involved in strategic psychosocial post-injury health care in most cases [3,12].

Injured people form a heterogeneous population because they vary widely in their physical, emotional, and social functioning [3,4,13,14]. Thus, different interventions and combinations of intervention core components are required for patient-centered counselling. Such a possibility to individualize the therapy or

counselling may be particularly crucial for injured people, who often experience a loss of resources and face new insecurities that may concern private as well as work-related aspects of life [15-17].

Even though there is evidence suggesting that injury rehabilitation interventions should broaden the treatment focus by fostering collaborative care [16,18,19], most of the existing studies only delivered specific standardized psychotherapeutic interventions targeting predominantly post-traumatic symptoms [20,21] or provided occupational therapy to enhance the work-reintegration rate [16,18]. However, the demand for a more holistic approach is in line with the culture shift observed in health management away from a biomedical towards a more inclusive biopsychosocial model [22,23]. For this reason, the collaborative-care-framework applied in the present study continuously involved patients, therapists and counsellors, physicians and rehabilitation specialists in decisions and treatments.

Previous studies on the effects of psychosocial interventions on injury rehabilitation show mixed results. For example, the results from a systematic review and meta-analysis regarding the effectiveness of early psychological interventions for psychological distress after injury indicate a reduced severity for symptoms of depression and post-traumatic stress disorder [6]. Yet, in another systematic review on psychosocial interventions following an accident-related injury, no treatment effects were found for a wide range of psychosocial outcomes in most of the included randomized controlled trials (RCT). The authors suggest that the lack of clear evidence might result from the high dropout rates observed in the reviewed studies [24]. As a means to help prevent high dropout rates, a screening was administered to all participants in this study. Based on the results of this screening, only people at high risk for a complicated adjustment process, i.e. a recovery or rehabilitation process that is

complicated by complex physical rehabilitation and / or psychological distress due to the accident, the resulting injury, or the challenges of the new situation after the accident, were asked to participate in the study.

Aims and Hypotheses

Therefore, the aim of this study was to examine the effectiveness of a newly developed, highly tailored psychological counseling intervention, selected on the basis of a screening risk profile [25] and aimed at improving well-being and work reintegration, within a collaborative care setting. We hypothesized that the newly developed multidisciplinary counselling intervention would have beneficial effects on well-being compared to the conventional case management-only approach. In line with current biopsychosocial models of disability, we further assumed that effective improvement of well-being can be seen as a more general measure of treatment efficacy. In contrast to existing studies, which mostly focused on one-dimensional outcomes [17,18,20,24,26], we evaluated five aspects of well-being related to different aspects of life. These aspects are (1) negative feelings, (2) life satisfaction, (3) job satisfaction, (4) family-related satisfaction, and (5) health-related satisfaction.

Methods

Trial Design

The study was designed as a randomized controlled trial consisting of an intervention group and a control group. The study population consisted of German speaking, adult workers (≥18 years) who suffered an accident within 3 months prior to the participation in this study. Ethical approval was obtained from the Ethics Committee of the University of Bern (No. 2011-04-172) and the study was registered at the ISRCTN registry (ISRCTN05534684). Furthermore, the study was monitored and

assessed by the Clinical Trial Unit Bern, an independent national clinical trial management facility coordinating patient-oriented clinical research.

The required sample size was estimated with an apriori power analysis using G*Power [27]. Assuming a small effect between the experimental and control group over time (f2 = 0.15, (α = 0.05, 1-β = 0.80), the required sample size was 164 participants (82 = per group).

Recruitment and Eligibility Criteria

Participants were consecutively recruited within the main agency of the Swiss Accident Insurance Fund (Suva) in Bern between September 2011 and September 2015. The Suva is the largest accident insurance company in Switzerland. Suva case managers were requested to apply the Work and Health Questionnaire (WHQ) [25] as a screening tool to all new claimants within the first 3 months after the accident. The WHQ is a 23-item questionnaire with two correlated subscales, which revealed satisfactory test criteria and a good predictive value to identify persons with a complicated work reintegration process in an insurance setting [28]. Today the questionnaire is used as a screening tool by case managers in two main agencies of the Suva. The questionnaire screens for (1) workplace characteristics, (2) cognitions about the future, (3) social support at work, (4) job characteristics, (5) distress at work, (6) pain, (7) post-traumatic symptoms, (8) anxiety, and (9) worries. The complete WHQ is displayed in Appendix 1. The cut-offs for a complicated recovery process were previously evaluated and showed good prognostic validity for the health subscale [Siegenthaler, 2010]. In this previous evaluation, the optimal cut-off for the health subscale was 0.3 using the formula $P(Y)=1/(1+e^{\wedge}(-(-3.317 - .010 \cdot H3 + .002 \cdot H4 + .004 \cdot H5 + .283 \cdot H6 + .289 \cdot H11 - .272 \cdot H10 + .255 \cdot H8 + .180 \cdot H7 + .915 \cdot H1 + .474 \cdot H2 + .125 \cdot H9$ and the optimal cut-off for the work subscale was 34.00 [28].

Claimants who exceeded one or both of these cut-offs were considered at risk for a complicated adjustment and rehabilitation process and were asked to participate in the study. Additionally, participants also had to (1) be at least 18 years old, (2) have a working disability causing a complete working incapacity, (3) have a permanent employment contract and (4) live in an area in, or up to 20 kilometres away from Berne to ensure a convenient accessibility to the interventions. Exclusion criteria were the presence of (1) severe injuries (e.g. head or spinal cord injuries), (2) occupationally related diseases (e.g. pulmonary illness) and (3) degenerative conditions (e.g. rheumatoid arthritis).

Randomization

Written informed consent was obtained from each participant prior to randomization. We ensured adequate allocation concealment by randomly allocating the participants using cards contained in sealed envelopes provided by the Clinical Trial Unit. The randomization procedure was concealed from the trial assessors. It was not feasible to blind the counsellors, occupational psychologists, clinical supervisors, case managers and the participants due to the nature of the intervention.

Procedure

Participants who exceeded the cut-off in the screening, met all inclusion criteria and gave their written informed consent were randomized to either the intervention group (IG) or the control group (CG). After randomization they were asked to fill out the baseline questionnaires (T0).

Both the participants of the IG and the CG received conventional case management, which represents care-as-usual (CAU). Based on the results of the screening, a tailored counselling intervention was derived for the participants in the IG. Participants whose screening results mainly indicated work-related distress received

occupational counselling. Participants whose screening results mainly indicated psychological distress received mental health counselling. If the cut-offs of the screening were exceeded in both areas, participants received both occupational and mental health counselling. Additionally, all participants in the IG received collaborative care that consisted of regular round table meetings with different representatives of the healthcare service (i.e. physicians, case managers, psychotherapists, occupational psychologists) to discuss the individual cases and determine optimal treatment steps. After the screening, the randomization and the baseline assessment (T0), participants were assessed again after 12 (T1) and 18-months (T2) post-injury.

Intervention

Conventional Case Management

All participants received conventional case management according to the SUVA's case management procedure (see [29] for more information). Trained case managers provided support and personal assistance concerning different aspects of work reintegration with the goal of a fast and long-lasting work-reintegration. This support included coordinating healthcare treatment, monitoring the progress and, if necessary, finding new work arrangements. The caseload was approximately 35 cases per case manager.

Mental Health Counselling

The mental health-counselling aimed at building on a participant's current individual strengths. Psychotherapists working at the outpatient psychotherapeutic facility of the Institute of Psychology at the University of Bern offered an integrative counselling based on the Consistency Theory [30]. The basic idea of this theory is that the therapeutic approach should be chosen to be complementary to a client's individual, temporarily unbalanced basic needs, i.e. the needs for (1) attachment, (2) control and

orientation, (3) pleasure gain or displeasure avoidance, and (4) self-enhancement. Thus, a better, more balanced fit between inner, psychological needs and the experience of reality should be promoted. This fit is called *consistency* [30]. This approach is theory-guided, but not manualized, since manualizing would contradict the theory's basic principle of an individual, complementary therapy approach. This principle of complementary therapy design according to the consistency theory was combined with cognitive behavioural techniques like psychoeducation, cognitive restructuring, and Socratic dialogues. Additionally, the therapists strongly focused on resource activation, the experience of mastery, problem actualization and clarification of conflicting beliefs [30,31]. Further, the interventions comprised educational, cognitive, and behavioural elements targeting the psychosocial adjustment process to the accident-caused injury and its consequences. For a precise description of the treatment guidelines, quality management and examples, please see [30].

At the first meeting, a Structured Clinical Interview (SCID-I) [32] was conducted by a staff member of the outpatient psychotherapeutic facility of the Institute of Psychology at the University of Bern. After this assessment, a therapist was assigned to the case who developed a case formulation and an individual treatment plan, followed by goal setting together with the respective participant within the next counselling sessions [30,33,34]. To ensure the therapists' treatment adherence to the aforementioned approach, all treatment sessions were videotaped, monitored, and regularly optimized by external supervisors [33].

Occupational Counselling

The occupational counselling was held at a private company specializing in coaching and human resources management as well as organizational processes [35]. To ensure a very flexible and highly individualized approach to this form of counselling as

well, an occupational psychologist first conducted work-related diagnostics (i.e. structured interviews, self-report questionnaires) and discussed individual life- and work-related goals with the participant. The diagnostic process was completed by a meeting with the participants' supervisor, and a structured observation of the participant's workplace to examine various adverse influences in a holistic and naturalistic way. These observations were then discussed with the superior resulting in a goal-oriented action plan consisting of a tailored job counselling, a leadership coaching and/or a guided reorganisation of the workplace. The participant was not involved in the development of their action plan.

For participants who were either unemployed or whose supervisor did not want to participate, no such structured observation was possible. In these cases, participants received job coaching focused on preparation for a new employment or a goal-oriented counselling to deal with difficulties in the workplace. Regardless of whether a participant received mental health counselling, occupational counselling, or both, treatment lasted as long as their assigned occupational psychologist, psychotherapist or case manager considered appropriate. Neither the mental health counselling nor the occupational counselling were by definition standardized, manualized treatments, as this would contradict the underlying approach of individualized, tailored treatment. However, the mental health counselling was based on Grawe's consistency theory [30] and in the occupational counselling the same components, which were then individualized, were used.

Outcomes

In addition to the above described screening, which was conducted with the WHQ, we assessed the following:

Life Satisfaction and negative Feelings

The Bern Questionnaire on Well-Being, adult form (BSW/A) [36] is a 39-item standardized psychological questionnaire assessing subjective well-being with two uncorrelated subscales (i.e. *life satisfaction, negative feelings*). Items are rated on six-point Likert scales and four-point Likert scales. Scores indicating a high degree of life satisfaction and the presence of more negative feelings, respectively. The questionnaire has obtained satisfactory psychometric properties concerning stability and validity [36,37]. The internal consistency of the subscales is satisfactory with Cronbach's α = 0.82 (*life satisfaction*) and α = 0.77 (*negative feelings*).

Job Satisfaction

We measured job satisfaction with the Short Job Satisfaction Questionnaire (AKZ) [38], which consist of 4 items rated on a 7-point Likert scale (1 = *most of the time* to 7 = *never*). High scores indicate a high degree of job satisfaction.

Family- and health-related Satisfaction

The Indicators of Rehab Status Questionnaire Version 3 (IRES-3) [39] is a self-assessment of a person's somatic, functional, and psychosocial rehabilitation status that is based on a theoretical model of rehabilitation [40]. We assessed the two subscales *family related satisfaction* and *health related satisfaction*. All items are rated on a 5-point Likert-scale. High scores on those subscales indicate lower family-related satisfaction and higher health-related satisfaction respectively. The internal

consistencies of all of the questionnaire's subscales range from good to very good with Cronbach's alpha values between 0.75 and 0.94 [39].

Statistical Analysis

Participants' characteristics were calculated at baseline using mean scores and standard deviations. Primary analyses were performed on the intention-to-treat (ITT) sample using all available data from all randomized participants. Results are reported according to the guidelines of the Consolidated Standards of Reporting Trials (CONSORT) checklist [41]. In order to accommodate between- and within-effects in light of missing data and unequal numbers of observations, we fitted linear mixed models to the longitudinal measures of the outcome variables as described in Singer and Willett [42]. The analyses were conducted using the R-package nlme [43] in R Statistical Language [44] using full maximum likelihood estimation. We confirmed the normal distribution of the outcome variables by inspecting the residual diagnostics of the fitted multilevel models.

For each outcome variable, the analysis proceeds through different steps according to the techniques described in Tasca and Gallop [45]. First, we estimated a null model (intercept only model) which allowed an estimation of the proportion of variation in the outcome variable that is between and within persons in the sample. The first model (unconditional growth model with random intercept) examined the within-person trajectories of change across sessions. The second model (conditional growth model with random intercept and cross level interaction) examined the effect of the intervention and the question whether the intervention had different rates of change across sessions. The slopes in all models were fixed since no model yielded significantly lower global fit indices when including random slopes. We calculated

Nagelkerke's pseudo-R2 statistics as global effect size and Cohens' d as a local effect size.

To test the accuracy and stability of our fitted multi-level models, we used multiple imputation to replace missing values. We followed the joint modelling paradigm and imputed all incomplete variables simultaneously with one statistical model [46-48]. All analyses were replicated individually across the imputed datasets, and multiple parameter estimates were combined using Rubin's rules for multiple imputation for missing data [49].

Results

Participant Flow and Characteristics

A total of 1499 applicants were pre-screened. 590 of them (39.4%) were considered to be at high risk for a complicated adaptation process, thereby qualifying them for a request to participate in the study. Out of these, 205 people (34.7%) fulfilled all inclusion criteria, gave their informed consent and consequently were randomized. The CONSORT-diagram shown in figure 1 displays the flow of participants throughout the study.

Figure 1

CONSORT flow chart of participants throughout the study
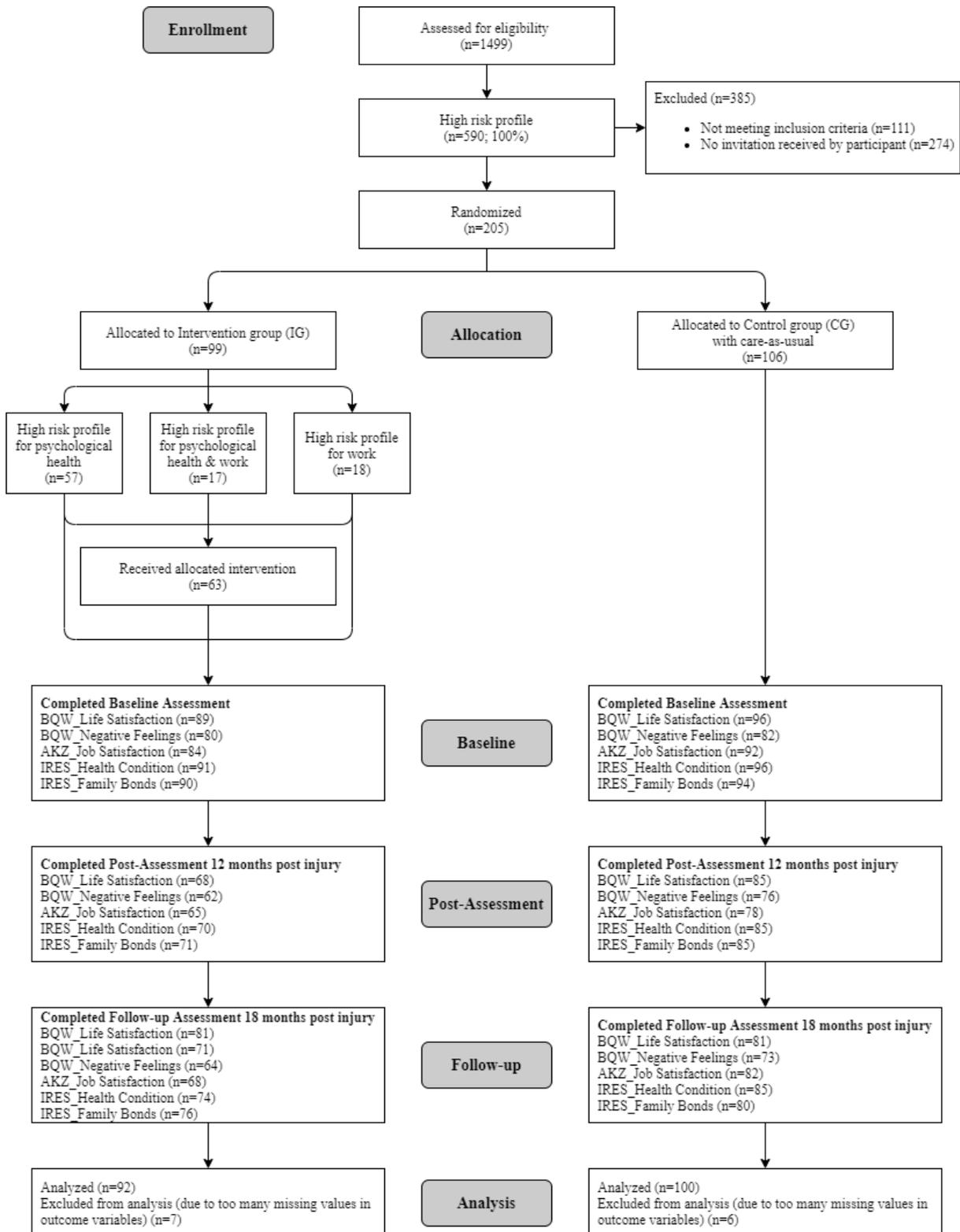
The majority of participants of the final sample were male ($n = 138$; 71.9%), and the average age was 49.8 years ($SD = 10.4$). Table 1 shows the demographic and clinical characteristics of all participants at baseline. We found no significant differences in baseline demographics or clinical variables between the two groups.

Table 1

Demographics and Clinical Characteristics of Participants

	Control Group		Intervention group		*t (df)*	χ² *(df)*	*p*
Age					**0.94** *(166.7)*		**0.35**
Mean *(SD)*	50.50	10.3	49.04	10.36			
Gender (%)						**0.58** *(1)*	**0.45**
Female	31	31.0	23	25.00			
Male	69	69.0	69	75.00			
Level of Education (%)						**0.70** *(2)*	**0.71**
No high school diploma	70	70.7	64	69.56			
High-School and above	25	25.2	26	28.26			
Others	4	4.05	2	2.17			
Annual Income at Baseline						**4.34** *(4)*	**0.36**
Up to CHF 40 000	6	6.19	7	8.14			
Up to CHF 60 000	21	21.6	16	18.60			
Up to CHF 80 000	30	30.9	30	34.88			
Up to CHF 100 000	27	27.8	15	17.44			
Over CHF 100 000	13	13.4	18	20.93			
Missing values	3		14				
Occupational						**1.31**	**0.25**
Blue-collar-worker	60	60.6	64	69.57			
White-collar-worker	39	39.3	28	30.43			
Accident Type (%)						**1.28** *(1)*	**0.26**
Recreational	70	76.0	60	67.42			
Work-related	22	23.9	29	32.58			
Missing values	8		3				
Injury Type (%)[1]							
Polytrauma	25	27.1	-	-			
Tendon rupture	22	23.9	-	-			
Fractures	19	20.6					
Bruises	6	6.53	-	-			
Other (i.e. burns, disc hernia, dislocations)	20	21.7 4	-	-			

Note. 1 = due to data protection policies injury types are known only for participants in the IG.
CG (*n* = 100), IG (*n* = 92), comparisons between groups are performed with two-sided Welch's
t-tests for continuous data and Yates continuity correction for the chi square test for categorical
variables.

A total of 13 participants (6.3%; IG = 7, CG = 6) had to be excluded from the final analyses because there were too many missing values. We compared these participants to the final sample (IG = 92; CG = 100) regarding all descriptive variables. Our analyses revealed no significant differences.

Of the 57 participants with a high-risk profile in mental health, a SCID interview was conducted with 33 participants (57.9%) while 24 participants (42.1%) refused to participate. Those participants who did the SCID received an average of 2.23 (SD = 6.94) counselling sessions of approximately 50 minutes. 30 (85.7 %) out of the 35 participants with a work-related high-risk profile received an occupational counselling session and a structured observational analysis of the workplace while 5 participants (14.3%) refused to participate. We found no significant association with any sociodemographic variable and non-compliance.

The different outcome measures, i.e. the questionnaires were filled out separately. Since not all participants filled out all questionnaires, the number of completers varies depending on the questionnaire. Correspondingly, there were 64 – 74 (69.6% – 80.4%) participants in the IG, and 73 – 85 (73% – 85%) participants in CG who participated up to and in the follow-up measurement, which can be seen in figure 1. Attrition did not differ by condition. A non-responder analysis revealed that non-responders were more likely to be female with respect to the following outcome variables: (1) life satisfaction ($\chi2(1)$= 4.31, p = .038), (2) negative feelings ($\chi2(1)$= 6.23, p = .013), (3) health-related satisfaction ($\chi2(1)$= 4.93, p = .026), and (4) family-related satisfaction ($\chi2(1)$= 4.93, p = .027). Moreover, low income was associated with not filling out the questionnaires for negative feelings ($\chi2(4)$= 18.36, p < .001), job satisfaction ($\chi2(4)$= 11.47, p = .016) and family-related satisfaction ($\chi2(4)$= 9.65, p = .047).

Treatment effects

For life satisfaction, the first model (unconditional growth model with random intercept) revealed a non-significant negative relationship between time and life satisfaction (b = -0.01, SE = .022, p = .576) suggesting that there is no time effect. The second model (conditional growth model with random intercept and cross level interaction) indicated non-significant negative relationships between time and life satisfaction (b = -0.05, SE =.030, p = .091) as well as between condition and life satisfaction (b = -0.11, SE = .110, p = .306). This result suggests that neither time nor the particular intervention have an effect on life satisfaction. Moreover, the effectiveness of treatment rated as change in life satisfaction was not significant (b = 0.08, SE = .044, p = .061) indicating that the intervention had no effect on life satisfaction over time (table 2).

Table 2

Results of the Multilevel Models for Change in Life Satisfaction across Time and Condition

	Life Satisfaction			Negative Feelings			Job Satisfaction			Family-related satisfaction			Health-related satisfaction		
Fixed Effects	*B*	*SE*	*t*	*B*	*SE*	t	*B*	*SE*	t	*B*	*SE B*	*t*	*B*	*SE B*	*t*
Intercept	4.54	0.08	59.39**	2.70	0.09	30.20**	4.73	0.12	40.90	3.15	0.08	36.31**	4.14	0.07	60.44***
Treatment	-	0.11	-1.03	0.02	0.13	0.13	-0.05	0.17	-1.00	-	0.13	-0.36	-0.05	0.10	-0.47
Time	-	0.03	-1.70	-0.02	0.04	-0.67	-0.06	0.06	-0.32	-	0.05	-3.90***	0.10	0.03	3.11**
Time x Treatment	0.08	0.04	1.88†	-0.14	0.05	-2.69***	0.02	0.09	0.25	0.02	0.07	0.26	0.08	0.05	-2.69†
Random Effects															
Intercept	0.44	[0.35- 0.55]		0.56	[0.44 -0.71]		0.75	[0.57- 1.00]		0.40	[0.30 - 0.53]		0.32	[0.25 - 0.41]	
Residual	0.15	[0.13- 0.18]		0.18	[0.15 - 0.22		0.58	[0.49 - 0.68]		0.37	[0.32 - 0.44]		0.16	[0.14 - 0.19]	
Model Fit	**Dev**	**AIC**	**BIC**	**Dev**	**AIC**	**BIC**	**Dev**	**AIC**	**BIC**	**Dev**	**AIC**	**BIC**	**Dev**	**AIC**	**BIC**
	861.	873.	898.5	875.	887.	911.9	1336.	134	1373.	116	1172.	1197.3	846	858	883

Note. 95% Confidence Intervals in parentheses; *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$; †$p < 0.07$; *Dev*= -2*Log Likelihood (LL) of the model; *AIC* = Akaike information criterion*; BIC* = Bayesian information criterion.

Next, we examined the within-person trajectories of change across sessions for negative feelings. The first model yielded a significant negative relationship between time and life satisfaction ($b = -0.09$, $SE = .027$, $p < .001$) suggesting that negative feelings in general decrease across time. The second model revealed a significant negative relationship of the time-condition-interaction ($b = -0.14$, $SE = .053$, $p < .008$) (table 2). This negative relationship indicates that participants in the IG experienced a significantly higher decrease in negative feelings over time compared to the participants in the CG. Cohens' d for baseline to follow-up was 0.11 in the CG, and 0.74 in the IG, which corresponds to small-to-medium effects.

Subsequently, we examined the within-person trajectories of change across sessions for job satisfaction. The first models revealed no significant relationships between time and job satisfaction ($b = -0.05$, $SE = .043$, $p = .258$), and of the time-condition-interaction ($b = 0.02$, $SE = .087$, $p = .802$). This result suggests that neither time nor the particular intervention have an effect on job satisfaction (table 2).

In a next step, we analyzed at the within-person trajectories of change across sessions for family-related satisfaction. The first model yielded a significant negative relationship between time and family-related satisfaction ($b = -0.18$, $SE = .034$, $p < .001$) suggesting that family-related satisfaction generally increases regardless of the condition across time. The second model examined the effect of the condition to evaluate whether the condition had different rates of change across sessions. The model revealed a non-significant negative relationship of the time-condition-interaction ($b = 0.02$, $SE = .069$, $p = .795$) suggesting that there is no effect of treatment on the trajectory (table 2).

Finally, we examined the within-person trajectories of change across time for health-related satisfaction. The first model yielded a significantly positive relationship between time

and health-related satisfaction ($b = 0.13$, $SE = .022$, $p < .001$) suggesting that health-related satisfaction increases regardless of the condition across time. The second model examined the effect of the condition to evaluate whether the condition had different rates of change across sessions. The model revealed a non-significant positive relationship of the time-condition-interaction ($b = 0.08$, $SE = .045$, $p = .071$) suggesting that treatment had no effect on the trajectory when it comes to health-related satisfaction (table 2).

Discussion

This study is the first RCT assessing the effects of a multidisciplinary counselling intervention for mildly-to-moderately injured workers. To the best of our knowledge, the present study is the first attempt to combine a fine-grained triage process with a highly individualized treatment approach [50]. Based on the results of the screening we developed and conducted an individually tailored intervention for injured workers with a high risk for a complicated rehabilitation process. Thereby, we aimed to address the participants' respective needs and to deliver counselling relevant to their personal situation. Participants were additionally assessed at baseline as well as after 12 and 18 months.

The main finding of this trial is the significant decrease of negative feelings in the counselled injured workers over time, whereas participants in the control group remained relatively stable. The effect size of Cohens $d = 0.74$ can be considered high. This finding is partially consistent with results of Pirente et al. [19] who found a significantly decreased frequency of depressed injured workers after an early CBT-oriented counselling intervention up to12 months post-injury.

The second important result of our trial is the observed significant improvement of both groups in health- and family-related satisfaction across all measurements. These effects indicate

a natural adaptation process over time. Previous studies have shown that a small fraction of severely injured people exhibit healthy long-term adjustment without any psychological support [3,4,14,51]. However, it can be argued that conventional case management, which the control group received as care-as-usual, is also a form of intervention [29]. Therefore, it cannot be determined exactly whether the improvement in terms of health- and family-related satisfaction is the result of a natural adaptation process or of the case management.

In contrast to our expectations, we found no significant differences between the two groups concerning life satisfaction, job satisfaction, health-related and family-related satisfaction. Several explanations may account for this lack of intervention effects on the different aspects of well-being. First, it seems particularly important that the potential of a complicated adjustment process regarding physical and psychological changes and distress in injured workers is recognized and treated as early after the accident as possible, since workers tend to be especially worried in this early phase [4]. Our intervention began at the earliest four months after the accident. Therefore, it is possible that the participants' initial worries about their financial and occupational future may have already diminished by the time the intervention began, as they have had to get used to their new situation for some time. In addition to the potentially late onset of treatment, a second reason could be that the treatment duration offered in our study was too short to produce significant effects. This possible explanation could be explored in another study with longer treatment durations. Third, there may be unexpected differential treatment effects that we could not have anticipated due to the novelty of our counselling intervention [30]. On the one hand, such treatment moderators are useful for identifying subgroups of injured people who respond preferentially to one treatment over another. On the other hand, they also have the potential to further reduce the effect sizes of

general treatment [52]. We have addressed this important research question concerning moderators in exploratory secondary analyses which are described in a separate paper.

Limitations and Strengths

There are several limitations that should be addressed. First, we were confronted with high dropout rates at all stages of our study (see figure 1). More precisely, a significant portion of the potential participants did not receive an invitation to participate. Due to privacy protection policies of the SUVA insurance company, we have no information about these individuals. However, a qualitative investigation together with the case managers showed that the acceptance for the study recruitment was already low in the first place. Therefore, we cannot determine with certainty whether or not these individuals differed significantly from our study population. Additionally, the relatively small sample size of 192 participants has resulted in lower statistical power, which could be a reason for our slightly insignificant results with respect to the two outcome variables life satisfaction ($p = .06$) and health-related satisfaction ($p = .07$).

After randomization, about a third (37.6 %) of the participants in the intervention group withdrew their participation. This is particularly surprising since we ensured convenient accessibility by only including people living close to the study center and by offering all treatment sessions free of charge. However, the observed overall non-compliance rate was similar to comparable studies [20]. Premature treatment withdrawal reported in other studies range from 10% to 50% across a variety of settings, patient groups and modalities [53]. Interestingly, the acceptability of the occupational counselling was significantly higher (85.7%) compared to the acceptability of the mental health counselling (44%). These results are consistent with the findings of Van der Klink et al. [54], which show that treatment acceptance can generally be higher for work-related interventions than for psychosocial interventions. This

may be explained by the persistent negative connotation of both mental disorders and psychotherapeutic interventions [55]. Work-related interventions on the other hand may be perceived as less threatening or stigmatizing. Thus, it might be useful to consider whether some elements of counselling, and mental-health counselling in particular, could be delivered in an alternative way. One such alternative approach comprises an online intervention, which targets important coping and problem-solving strategies, resource activation and cognitive restructuring. In this context, the need for more research to investigate reasons for withdrawal and dropouts is also worth mentioning. In addition to research on new programs and interventions, an increasing number of studies examine how commitment and acceptance can be fostered or how dropout rates can be reduced [56-59]. Furthermore, additional studies should explore the intervention feasibility in more detail.

Another limitation of this study is that the interventions were not standardized because we did not provide a treatment manual. This unstandardized approach may limit the utility of our treatment efficacy evaluation [11]. Nevertheless, the freedom and flexibility of treatment in our intervention is in line with the nature of the applied approach by Grawe [30]. He hypothesizes that a highly flexible employment of psychotherapeutic common factors adapted complementary to the individual patient's needs results in better treatment success. In a similar manner, there is some evidence of undesirable effects of manual adherence in standardized and manualized interventions with injured people [20]. The trade-off between flexibility and standardization evident in our paper is the subject of diverse studies and presents a variation on the question of how to unite practice and research. Thus, more research like ours is needed to examine complex real-world processes through smart and methodologically sound designs to make more accurate statements about this freedom-flexibility trade-off.

From a methodological perspective, one strength of this study is its high methodologic quality as it met several Cochrane collaboration criteria (i.e. randomization concealment, ITT principle, loss to follow-up lesser than 50%, trial assessor blinded from data collection process, external assessment centre for clinical trials). In contrast to previous studies [13,17,18,20,21,26], we applied a more robust statistical method, which takes the hierarchical structure of the data into account and improves the handling of missing data [42,43,45,46]. Furthermore, we ensured high quality treatment and implementation by engaging experienced psychotherapists and occupational psychologists and by providing regular supervision based on the videotaped counselling sessions [11,33] and patient feedback [30].

Despite all limitations, our findings suggest that a highly tailored counselling intervention for people who were injured in an accident is partly useful to prevent psychological sequelae in terms of negative feelings while enhancing well-being. This is an important finding that should be taken into account in the rehabilitation of injured workers.

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Authors' Contributions

This study was conceptualised by HJZ, VS and UHR but all authors contributed equally to the final methodology. HJZ, VS, UHR recruited the participants. VS and HJZ supervised the interventions. SA performed data collection and analysis. SA, HJZ and JH interpreted the analyses. JH drafted the manuscript. All authors significantly contributed to the writing of the

manuscript. The manuscript was reviewed and edited prior to submission and all authors agreed to the final version.

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Declaration of Interest

The authors report no conflicts of interest.

References

1. Egli S. Unfall oder Krankheit? Das is hier die Frage [Accident or illness? That is the question!] 2018 [cited 2021 13 July]. Available from: https://www.suva.ch/de-ch/news/2018/unfall-oder-krankheit

2. Bundesgesetz über den Allgemeinen Teil des Sozialversicherungsrechts [Federal Law on the General Part of Social Insurance Law], 830.1. Sect. 4 (2000).

3. Kendrick D, Kelllezi B, Coupland C, et al. Psychological morbidity and health-related quality of life after injury: multicentre cohort study. Quality of Life Research. 2017 2017/05/01;26(5):1233-1250.

4. Lange C, Burgmer M, Braunheim M, et al. Prospective Analysis of Factors Associated with Work Reentry in Patients with Accident-Related Injuries. Journal of occupational rehabilitation. 2007 2007/03/01;17(1):1-10.

5. Bryant RA, O'Donnell ML, Creamer M, et al. The psychiatric sequelae of traumatic injury. American Journal of Psychiatry. 2010;167(3):312-320.

6. Giummarra MJ, Lennox A, Dali G, et al. Early psychological interventions for posttraumatic stress, depression and anxiety after traumatic injury: A systematic review and meta-analysis. Clinical psychology review. 2018 Jun;62:11-36.

7. Shalev AY, Ankri Y, Israeli-Shalev Y, et al. Prevention of posttraumatic stress disorder by early treatment: results from the Jerusalem Trauma Outreach And Prevention study. Archives of general psychiatry. 2012 Feb;69(2):166-76.

8. Brunet A, Des Groseilliers IB, Cordova MJ, et al. Randomized controlled trial of a brief dyadic cognitive-behavioral intervention designed to prevent PTSD. Eur J Psychotraumatol. 2013;4.

9. Munder T, Flückiger C, Leichsenring F, et al. Is psychotherapy effective? A re-analysis of treatments for depression. Epidemiology and Psychiatric Sciences. 2019;28(3):268-274.

10. Pybis J, Saxon D, Hill A, et al. The comparative effectiveness and efficiency of cognitive behaviour therapy and generic counselling in the treatment of depression: evidence from the 2nd UK National Audit of psychological therapies. BMC Psychiatry. 2017 2017/06/09;17(1):215.

11. Chambless DL, Hollon SD. Defining empirically supported therapies. Journal of Consulting and Clinical Psychology. 1998;66(1):7-18.

12. Mayou RA, Ehlers A, Bryant B. Posttraumatic stress disorder after motor vehicle accidents: 3-year follow-up of a prospective longitudinal study. Behaviour research and therapy. 2002 Jun;40(6):665-75.

13. Holmes A, Hodgins G, Adey S, et al. Trial of interpersonal counselling after major physical trauma. Aust N Z J Psychiatry. 2007 Nov;41(11):926-33.

14. Bonanno GA, Kennedy P, Galatzer-Levy IR, et al. Trajectories of resilience, depression, and anxiety following spinal cord injury. Rehabil Psychol. 2012 Aug;57(3):236-47.

15. Ogawa T, Omon K, Yuda T, et al. Short-term effects of goal-setting focusing on the life goal concept on subjective well-being and treatment engagement in subacute inpatients: a quasi-randomized controlled trial. Clin Rehabil. 2016 Sep;30(9):909-20.

16. Cullen KL, Irvin E, Collie A, et al. Effectiveness of Workplace Interventions in Return-to-Work for Musculoskeletal, Pain-Related and Mental Health Conditions: An Update of the Evidence and Messages for Practitioners. Journal of occupational rehabilitation. 2018 Mar;28(1):1-15.

17. O'Donnell ML, Lau W, Tipping S, et al. Stepped early psychological intervention for posttraumatic stress disorder, other anxiety disorders, and depression following serious injury. J Trauma Stress. 2012 Apr;25(2):125-33.

18. Bültmann U, Sherson D, Olsen J, et al. Coordinated and tailored work rehabilitation: a randomized controlled trial with economic evaluation undertaken with workers on sick leave due to musculoskeletal disorders. Journal of occupational rehabilitation. 2009 Mar;19(1):81-93.

19. Pirente N, Blum C, Wortberg S, et al. Quality of life after multiple trauma: the effect of early onset psychotherapy on quality of life in trauma patients. Langenbecks Arch Surg. 2007 Nov;392(6):739-45.

20. Tecic T, Schneider A, Althaus A, et al. Early short-term inpatient psychotherapeutic treatment versus continued outpatient psychotherapy on psychosocial outcome: a randomized controlled trial in trauma patients. J Trauma. 2011 Feb;70(2):433-41.

21. Zatzick D, Roy-Byrne P, Russo J, et al. A randomized effectiveness trial of stepped collaborative care for acutely injured trauma survivors. Archives of general psychiatry. 2004 May;61(5):498-506.

22. Wade DT, Halligan PW. The biopsychosocial model of illness: a model whose time has come. Clin Rehabil. 2017 Aug;31(8):995-1004.

23. Schultz IZ, Stowell AW, Feuerstein M, et al. Models of return to work for musculoskeletal disorders. Journal of occupational rehabilitation. 2007 Jun;17(2):327-52.

24. De Silva M, Maclachlan M, Devane D, et al. Psychosocial interventions for the prevention of disability following traumatic physical injury. The Cochrane database of systematic reviews. 2009 Oct 7;2009(4):Cd006422.

25. Abegglen S, Hoffmann-Richter U, Schade V, et al. Work and Health Questionnaire (WHQ): A Screening Tool for Identifying Injured Workers at Risk for a Complicated Rehabilitation. Journal of occupational rehabilitation. 2017 Jun;27(2):268-283.

26. Zinman A, Digout N, Bain P, et al. Evaluation of a community reintegration outpatient program service for community-dwelling persons with spinal cord injury. Rehabil Res Pract. 2014;2014:989025.

27. Faul F, Erdfelder E, Buchner A, et al. Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses [journal article]. Behavior Research Methods. 2009 November 01;41(4):1149-1160.

28. Siegenthaler FM. Psychische Gesundheit und Rückkehr zur Arbeit von Verletzten nach leichten und moderaten Unfallereignissen –Prädiktoren für die Früherkennung komplizierter Heilungsverläufe [Dissertation]. Bern: University of Bern; 2011.

29. Scholz SM, Andermatt P, Tobler BL, et al. Work Incapacity and Treatment Costs After Severe Accidents: Standard Versus Intensive Case Management in a 6-Year Randomized Controlled Trial. Journal of occupational rehabilitation. 2016 Sep;26(3):319-31.

30. Grawe K. Psychological therapy. Toronto (CA): Hofrefe & Huber; 2004.

31. Gassmann D, Grawe K. General change mechanisms: the relation between problem activation and resource activation in successful and unsuccessful therapeutic interactions. Clinical psychology & psychotherapy. 2006;13(1):1-11.

32. Sass H, Wittchen HU, Zaudig M. Diagnostisches und statistisches Manual psychischer Störungen [Diagnostic and statistical manual of mental disorders text revision (DSM‐IV)]. Göttingen: Hogrefe; 2001. German.

33. Grawe K, Baltensperger C. Figurationsanalyse - ein Konzept und Computerprogramm für die Prozeß- und Ergebnisevaluation in der Therapiepraxis [Figuration analysis – concept and computer program for quality management in psychotherapy]. In: Laireiter AR, Vogel H, editors. Qualitätssicherung in der Psychotherapie und psychosozialen Versorgung – Ein Werkstattbuch [Quality assurance in psychotherapy and psychosocial care - A workshop book]. Tübingen: dgvt; 1998. p. 179-207.

34. Kiresuk TJ, Smith A, Cardillo JE. Goal Attainment Scaling: Applications, Theory, and Measurement. Taylor & Francis; 2014.

35. cpmo. Centrum für PersonalManagement und Organisationsgestaltung Bern2015 [cited 2020 02. November]. Available from: https://cpmo.ch/

36. Grob A, Lüthi K, Kaiser FG. Berner Fragebogen zum Wohlbefinden Jugendlicher (BFW) [The Bern Subjective Well-Being Questionnaire on Adolescents (BFW)]. Diagnostica. 1991;37(1):66-75.

37. Grob A. Subjective well-being and significant life-events across the life span. Swiss Journal of Psychology/Schweizerische Zeitschrift für Psychologie/Revue Suisse de Psychologie. 1995.

38. Baillod J, Semmer N. Fluktuation und Berufsverläufe bei Computerfachleuten [Turnover and career paths of computer specialists]. Zeitschrift für Arbeits-und Organisationspsychologie. 1994.

39. Bührlen B, Gerdes N, Jäckel W. Entwicklung und psychometrische Testung eines Patientenfragebogens für die medizinische Rehabilitation (IRES-3) [Development and psychometric testing of a patient questionnaire for medical rehabilitation (IRES-3)]. Die Rehabilitation. 2005;44(02):63-74.

40. Gerdes N, Weis J. Zur Theorie der Rehabilitation [On the theory of rehabilitation]. Grundlagen der Rehabilitationswissenschaften Themen, Strategien und Methoden der Rehabilitationsforschung [Basics of rehabilitation science: topics, strategies and methods of rehabilitation research]. Berlin: Springer; 2000. p. 41-68.

41. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. Bmj. 2010 Mar 23;340:c332.

42. Singer JD, Willett JB, Willett JB. Applied longitudinal data analysis: Modeling change and event occurrence. Oxford university press; 2003.

43. Pinheiro J, Bates D, DebRoy S, et al. nlme: linear and nonlinear mixed effects models 2018.

44. R Core Team. R: A language and environment for statistical computing. R Foundation for Statistical Computing. Vienna Austria: 2018.

45. Tasca GA, Gallop R. Multilevel modeling of longitudinal data for psychotherapy researchers: I. The basics. Psychother Res. 2009 Jul;19(4-5):429-37.

46. Little RJA. A Test of Missing Completely at Random for Multivariate Data with Missing Values. Journal of the American Statistical Association. 1988 1988/12/01;83(404):1198-1202.

47. Schafer JL, Graham JW. Missing data: Our view of the state of the art. Psychological Methods,. 2002;7(2):147–177.

48. 48.   Grund S, Robitzsch A, Luedtke O. mitml: Tools for Multiple Imputation in Multilevel Modeling.   0.4-1. 2018.

49. Schafer JL, Olsen MK. Multiple Imputation for Multivariate Missing-Data Problems: A Data Analyst's Perspective. Multivariate Behav Res. 1998 Oct 1;33(4):545-71.

50. Beutler LE, Mohr DC, Grawe K, et al. Looking for differential treatment effects: Cross-cultural predictors of differential psychotherapy efficacy. Journal of Psychotherapy Integration. 1991;1(2):121.

51. Quale AJ, Schanke AK. Resilience in the face of coping with a severe physical injury: a study of trajectories of adjustment in a rehabilitation setting. Rehabil Psychol. 2010 Feb;55(1):12-22.

52. Bodner TE. Estimating and testing for differential treatment effects on outcomes when the outcome variances differ. Psychol Methods. 2018 Mar;23(1):125-137.

53. Kegel AF, Flückiger C. Predicting Psychotherapy Dropouts: A Multilevel Approach. Clinical psychology & psychotherapy. 2015 Sep-Oct;22(5):377-86.

54. van der Klink JJ, Blonk RW, Schene AH, et al. The benefits of interventions for work-related stress. Am J Public Health. 2001 Feb;91(2):270-6.

55. Vogel DL, Heimerdinger-Edwards SR, Hammer JH, et al. "Boys don't cry": examination of the links between endorsement of masculine norms, self-stigma, and help-seeking attitudes for men from diverse backgrounds. J Couns Psychol. 2011 Jul;58(3):368-382.

56. van Ballegooijen W, Cuijpers P, Van SA, et al. Adherence to internet-based and face-to-face cognitive behavioural therapy for depression: a meta-analysis. PLoS One. 2014;9.

57. Alfonsson S, Johansson K, Uddling J, et al. Differences in motivation and adherence to a prescribed assignment after face-to-face and online psychoeducation: an experimental study. BMC psychology. 2017;5(1):3-3.

58. Alfonsson S, Olsson E, Hursti T. Motivation and Treatment Credibility Predicts Dropout, Treatment Adherence, and Clinical Outcomes in an Internet-Based Cognitive Behavioral

Relaxation Program: A Randomized Controlled Trial [Original Paper]. Journal of medical Internet research. 2016;18(3):e52.

59. Lin J, Faust B, Ebert DD, et al. A Web-Based Acceptance-Facilitating Intervention for Identifying Patients' Acceptance, Uptake, and Adherence of Internet- and Mobile-Based Pain Interventions: Randomized Controlled Trial [Original Paper]. Journal of medical Internet research. 2018;20(8):e244.

60. Prümper J, Hartmannsgruber K, Frese M. KFZA. Kurz-Fragebogen zur Arbeitsanalyse. European Economic Review - EUR ECON REV. 1995 01/01;39:125-131.

61. Haarhaus B. Entwicklung und Validierung eines Kurzfragebogens zur Erfassung von allgemeiner und facettenspezifischer Arbeitszufriedenheit. Diagnostica. 2016;62(2):61-73.

62. Strohm O, Ulich E. Unternehmen arbeitspsychologisch bewerten: ein Mehr-Ebenen-Ansatz unter besonderer Berücksichtigung von Mensch, Technik und Organisation. Vol. 10. vdf Hochschulverlag AG; 1997.

63. Hetzel C, Alles T, Bühne D, et al. Salutogenetische subjektive Arbeitsanalyse (SALSA) – Replikationsstudie zu Struktur, Validität und Kürzungspotenzialen. Prävention und Gesundheitsförderung. 2020 2020/05/01;15(2):136-142.

64. Stieglitz RD, Nyberg E, Albert M, et al. Entwicklung eines Screeninginstrumentes zur Identifizierung von Risikopatienten für die Entwicklung einer Posttraumatischen Belastungsstörung (PTB) nach einem Verkehrsunfall. Zeitschrift für Klinische Psychologie und Psychotherapie. 2002 2002/01/01;31(1):22-30.

65. Pfingsten M, Kröner-Herwig B, Leibing E, et al. Validation of the German version of the Fear-Avoidance Beliefs Questionnaire (FABQ). European Journal of Pain. 2000 2000/09/01/;4(3):259-266.

66. Williamson E. Fear avoidance beliefs questionnaire (FABQ). Aust J Physiother. 2006;52(2):149.

67. Snaith RP. The Hospital Anxiety And Depression Scale. Health and Quality of Life Outcomes. 2003 2003/08/01;1(1):29.

68. Hinz A, Brähler E. Normative values for the Hospital Anxiety and Depression Scale (HADS) in the general German population. Journal of Psychosomatic Research. 2011 2011/08/01/;71(2):74-78.

69. Mittag O, Glaser-Möller N, Ekkernkamp M, et al. Prädiktive Validität einer kurzen Skala zur subjektiven Prognose der Erwerbstätigkeit (SPE-Skala) in einer Kohorte von LVA-Versicherten mit schweren Rückenschmerzen oder funktionellen Beschwerden der inneren Medizin. Sozial- und Präventivmedizin. 2003 2003/12/01;48(6):361-369.

70. Schmitz N, Hartkamp N, Kiuse J, et al. The Symptom Check-List-90-R (SCL-90-R): A German validation study. Quality of Life Research. 2000 2000/03/01;9(2):185-193.

71. Derogatis LR, Unger R. Symptom Checklist-90-Revised.

Appendix

Work and Health Questionnaire (WHQ); English Version

	Item Formulation	**Rating Scale**	**Adopted from Scale**
WHQ_Work			
W1	Can you independently plan and organize your work?	Likert Scale (1–5)	KFZA
W2	Can you learn something new in your job?	Likert Scale (1–5)	KFZA
W3	In my job, I can see from the result whether my work was good or not.	Likert Scale (1–5)	KFZA
W4	In my work I can carry out a working task, from A to Z.	Likert Scale (1–5)	SALSA
W5	My job is not ideal, but it could be even worse.	Likert Scale (1–7)	AZK
W6	I have too much work.	Likert Scale (1–5)	KFZA
W7	Needed information or working tools (e.g., computer) are often not available.	Likert Scale (1–5)	KFZA
W8	I am often interrupted in my work (e.g., telephone calls).	Likert Scale (1–5)	KFZA
W9	The working conditions at my workplace are unfavorable. There are disturbances, such as	Likert Scale (1–5)	KFZA
W10	In case of any difficulties, I can rely on my colleagues.	Likert Scale (1–5)	KFZA

W11	In case of any difficulties, I can rely on my boss/supervisor.	Likert Scale (1–5)	KFZA
W12	I always get a feedback about the quality of my work from my colleagues or my supervisor.	Likert Scale (1–5)	KFZA

WHQ_Health

H1	Did you feel helpless during or after the accident?	0, 1	PTBS
H2	Do pictures about it (the accident) pop up into your mind?	0, 1	PTBS
H3	How would you describe your actual general health condition?	VAS (0-100)	IRES
H4	How often did you suffer from pain recently?	VAS (0-100)	IRES
H5	How much do you feel that this pain affects your daily life?	VAS	IRES
H6	I think that I am not able to work normally within 3 months.	Likert Scale (0-6)	FABQ
H7	(In the past week) I felt as if I am slowed down.	Likert Scale (0-3)	HADS
H8	(In the past week), worrying thoughts go through my mind.	Likert Scale (0-3)	HADS
H9	Have you recently been worrying about earning less in the future because of the	Likert Scale (0-3)	SPE
H10	How much were you bothered or distressed over the past 7 days by feeling lonely?	Likert Scale (0-4)	SCL-90

| H11 | How much were you bothered or distressed over the past 7 days by feeling fearful? | Likert Scale (0-4) | SCL-90 |

Note. *VAS* Visual Analog Scale, KFZA Kurzfragebogen zur Arbeitsanalyse [60], AKZ Arbeitszufriedenheitsskala [38,61], SALSA Salutogenetische subjektive Arbeitsanalyse [62,63], PTSB Screening Posttraumatische Belastungsstörung [64], IRES Indikatoren des Reha-Status [39], FABQ Fear Avoidance Belief Questionnaire [65,66], HADS Hospital Anxiety Depression Scale [67,68], SPE Skala zur Messung der subjektiven Prognose der Erwerbstätigkeit [69], SCL-90 Symptom Checklist 90 [70,71].

2.2 Article 2: Coping styles and optimism predict different aspects of well-being in a randomised controlled trial of a tailored counselling intervention for injured workers

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Coping styles and optimism predict different aspects of well-being in a randomized controlled trial of a tailored counselling intervention for injured workers

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Abstract

Objective: Many injured people suffer from reduced well-being and emotional distress even with mild to moderate accident-related injuries. This study aimed to identify moderators of treatment efficacy of a highly tailored multidisciplinary counselling intervention for injured workers.

Methods: We conducted exploratory moderator analyses of a prospective randomized controlled trial with 192 minor-to-moderately injured workers (71.9% male; M_{age} = 50) who were randomized to either a control group with case management only, or an intervention group with case management plus tailored counselling intervention. Seven moderators, including five coping styles, as well as dispositional optimism and pessimism, were assessed at baseline. The outcome measures, assessed at baseline as well as 12 months (post measure) and 18 months (follow-up measure) post-injury, concerned five aspects of well-being: job and life satisfaction, negative feelings, well-being related to family and personal health.

Results: We found differential treatment effects, as participants low in social diversion (d = .26), high in emotion-oriented coping (d = .64), and low in optimism (d = .48) benefited from the tailored counselling intervention and showed enhanced well-being in different aspects of life. No other effects were significant.

Conclusion: The results suggest that our tailored counselling intervention has a modest effect on negative feelings for minor to moderately injured workers. Generally, dispositional optimism and coping styles should be considered in rehabilitation interventions of injured workers.

Keywords: Coping; Counselling; Injury; Rehabilitation; Optimism; Well-being

Introduction

An accident is defined as a sudden, unintentional, harmful impact of an unusual external factor on the human body resulting in impairment of physical, mental, and psychological health according to both the Swiss National Insurance Fund (Suva) and Swiss law. This definition includes recreational as well as work-related accidents but distinguishes accidents from illness and other forms of injury (Egli, 2018). Although many people who suffer an accident recover well and quickly, a significant proportion experience decreased well-being, prolonged working disability and emotional distress even in cases of minor to moderate accident-caused injuries (Kendrick, Coupland, et al., 2017; Kendrick, Kelllezi, et al., 2017). However, injured people often receive only fragmented care (Kendrick, Kelllezi, et al., 2017). Since accident-caused injuries may encompass numerous issues and can lead to just as many physical and psychological sequelae, there is a need for more, flexible and individually tailored treatment options to meet the heterogeneity of complications.

The results of previous injury rehabilitation studies suggest that interventions should promote collaborative care, thereby broadening the treatment focus and applying a holistic bio-psycho-social perspective (e.g., Bültmann et al., 2009; Cullen et al., 2018; Zatzick et al., 2004). This is further supported by findings that injured or ill workers can best return to work when involved individuals and stakeholders work collaboratively (Russell & Kosny, 2019).

In an effort to address this need, we conducted a randomized controlled trial (RCT) to investigate the efficacy of a highly tailored psychological counselling intervention (Hegy et al., 2021). Despite applying collaborative care and tailoring, we only found significant improvement in one of the five assessed domains of well-being: Participants in the intervention group (IG) showed a significant decrease in negative feelings up until 18-monts post-injury, with a moderate

effect size ($d = .74$), compared to the participants in the Control group (CG). Due to this overall rather limited effect, we decided to investigate possible moderators of the treatment. In addition to examining an intervention's effectiveness, the question of potential moderators, i.e., what works best for whom, is a key aspect of intervention research (Grawe, 1997, 2004; Kraemer et al., 2002; Tornås et al., 2019). Knowledge of patient characteristics that moderate treatment outcomes could help personalize psychosocial rehabilitation treatment. However, to the best of our knowledge, no studies have evaluated treatment moderators for psychosocial rehabilitation interventions for the heterogeneous population of minor to moderately injured workers. In accordance with the biopsychosocial model of disability (Wade & Halligan, 2004, 2017), the evaluation of treatment moderators may provide unique, new and valuable information to guide further treatment decisions.

An additional factor supporting the examination of potential treatment moderators are the high attrition rates often reported in injury rehabilitation interventions (De Silva et al., 2009; Giummarra et al., 2018; Tecic et al., 2011). For example, in a review of five studies of psychosocial injury rehabilitation interventions, da Silva et al. (2009) reported attrition rates ranging from 47% to 66%. To prevent early treatment termination, the authors recommend conducting a reliable screening of the injured individuals as well as gaining a deeper understanding of differential treatment effects.

We implemented both of these recommendations, with the recommendation to gain a deeper understanding of treatment effects constituting the aim of the current study. More specifically, we examined moderators of treatment outcome by means of secondary exploratory analyses of the data of our aforementioned RCT (Hegy et al., 2021). Due to the lack of studies regarding moderators of treatment success of injury rehabilitation interventions, we adopted a

hypothesis-generating approach with an exploratory analysis. We selected seven well-established

predictors of adaptation to health-related adversities and of psychosocial treatment success that

could generate specific hypotheses for further studies of differential treatment effects in injury

rehabilitation (Livneh & Martz, 2014; Skogstad et al., 2014; Tough et al., 2017; Vassend et al.,

2011). Those seven predictors consisted of five coping styles, dispositional optimism, and

dispositional pessimism.

Coping has been shown to influence the relationship between stressful life events and

physical and psychological functioning by mitigating how a stressful life event is perceived and

handled (Archer et al., 2019; Higgins & Endler, 1995; Langford et al., 2017; Tein et al., 2000).

Since all people encounter challenges at some point in their lives, the way in which stressful

events are dealt with and related to this, how well-being is achieved or regained, is of great

importance (Marroquín et al., 2017). In their seminal work, Lazarus and Folkman define coping

as "constantly changing cognitive and behavioral efforts to manage specific external and internal

demands that are appraised as taxing or exceeding the resources of the person" (Lazarus &

Folkman, 1984, p. 141). Based on this definition, it follows that coping can take different forms.

These different forms are referred to as *coping styles*. Thus, we examined different coping styles,

more specifically (1) *task-orientation,* (2) *emotion-orientation,* (3) *avoidance-orientation: social

diversion* as possible moderators of treatment on psychological well-being.

Coping styles can be influenced by different factors such as personality dispositions and

traits, personal resources and beliefs about the self and the world (Lazarus, 2006). Defined as a

personality trait reflecting a favorable orientation to their future (Carver et al., 2010),

dispositional optimism has been found to be a resource for different work and health related

factors. For example, higher levels of dispositional optimism have been associated among other

things with improved psychological functioning, adjustment following injury, and earlier return to work (Cancelliere et al., 2016; Myhren et al., 2010; Wadey et al., 2013). Therefore, we decided to assess *generalized dispositional optimism* and its counterpart, *generalized dispositional pessimism*, as the sixth and seventh possible moderators.

Methods

The data used in the current study were collected in an RCT investigating the effects of a tailored multidisciplinary counselling intervention with the aim support the adjustment process of injured workers (Hegy et al., 2021). We obtained ethical approval from the Ethics Committee of the University of Bern (No. 2011-04-172) and registered the study at the ISRCTN registry (ISRCTN05534684). The Clinical Trial Unit Bern, an independent national clinical trial management facility to coordinate patient-oriented clinical research, monitored and assessed the study.

Recruitment and Eligibility Criteria

The study population consisted of German speaking, adult workers (≥18 years) who suffered an accident within 3 months prior to study participation. Participants were consecutively recruited in a main agency of the Suva, the largest accident insurance company in Switzerland, with an average coverage of about 50% of all employees. Suva case managers were requested to screen all eligible claimants for the risk of a complicated rehabilitation process with an evaluated screening tool (Abegglen et al., 2017) within the first three months post-injury. Claimants were excluded if they were suffering from (1) severe injuries (e.g., head or spinal cord injuries), (2) occupationally related illnesses (e.g., pulmonary illness), or (3) degenerative conditions (e.g., rheumatoid arthritis). To be included, claimants further had to (1) be at least 18 years old, (2) have a working disability causing a complete working incapacity, (3) have a permanent

employment contract and (4) live in an area in, or up to 20 kilometers away from Berne to ensure a convenient accessibility to the interventions.

Procedure

Suva claimants whose screening showed an increased risk for a complicated rehabilitation process were asked to participate in the study. Of those, claimants who gave written informed consent, fulfilled all inclusion criteria, and did not fulfill any of the exclusion criteria, were eligible to participate in the RCT and thus randomized to either the IG or CG. Participants in the CG received only conventional case management according to the Suva's case management procedure(Scholz et al., 2016), which comprised the standard treatment (care-as-usual, CAU). Trained and experienced case managers provided support and personal assistance in all aspects of rehabilitation and work reintegration with the primary aim of a fast and long-lasting work reintegration. In addition to CAU, participants in the IG also received a tailored counselling intervention and collaborative care.

The intervention was created individually for each participant based on the screening results and thus tailored to their requirements. If the screening results mainly indicated work-related distress, the participant received occupational counselling, which consisted of work-related diagnostics and a discussion of the participant's life and work-related goals, followed by a structured observation of the workplace and a tailored job counselling. If the screening results mainly indicated psychological distress, the participant received mental health counselling, which consisted of integrative counselling including educational, cognitive, and behavioral elements to support the psychosocial adaptation process to the accident-caused injury. If the screening indicated both work-related and psychological distress, the participant received both occupational and mental health counselling. Both the occupational and the mental health

intervention focused on individual resource activation (Flückiger et al. 2010, Grawe, 2004) and life goal setting (Rose et al., 2017).

After the randomization, participants were asked to fill the baseline questionnaire (T0) and were assessed again 12 (T1) and 18-months (T2) post-injury.

Outcomes

We assessed five different aspects of subjective well-being as main outcomes. The first two aspects of subjective well-being were *life satisfaction* and *negative feelings*, which we both assessed with the two uncorrelated subscales of the Bern Questionnaire on Well-Being adult form (BSW/A; Grob et al., 1991). Items are rated on six-point Likert scales and four-point Likert scales. The questionnaire has obtained satisfactory psychometric qualities concerning stability and validity (Grob et al., 1991). The internal consistency of the subscales is satisfactory with Cronbach's α = .82 (life satisfaction) and α = .77 (negative feelings). As a third aspect of subjective well-being, we assessed *job satisfaction* by a single item of the Short Job Satisfaction Questionnaire (AZK; Baillod & Semmer, 1994): "If there is no change of my work conditions sooner or later, I will look for a new job." The answer was rated on a seven-point Likert scale. To assess the fourth and fifth aspects of subjective well-being, namely *family-related satisfaction* and *health-related satisfaction*, we used the two corresponding subscales of the Rehab Status Questionnaire Version 3 (IRES-3; Bührlen et al., 2005). All items of those two subscales are rated on 5-point Likert-scales with high scores indicating lower family-related satisfaction and higher health-related satisfaction, respectively. The internal consistencies of all the questionnaire's subscales range from good to very good with Cronbach's α between 0.75 and 0.94.

Of particular relevance to the present study are the potential moderators of treatment outcomes that were assessed. These included different coping styles and generalized dispositional optimism and pessimism. We assessed three different coping styles: (1) task-oriented coping (Cronbach's α = .83), (2) emotion-oriented coping (Cronbach's α = .80) and (3) avoidance by social diversion (Cronbach's α = .80) with the German short version of the Coping Inventory for Stressful Situations (CISS; Kälin, 1995). Participants rated the extent to which they use these coping styles with 18 items using 5-point Likert scales. The generalized dispositional optimism and pessimism were assessed with the German Version of the Life Orientation Test Revised (LOT-R; Glaesmer et al., 2008). The LOT-R consists of 10 items that are rated on a 5-point Likert-scale of which 3 items each are analysed for optimism (Cronbach's α = .69) and pessimism (Cronbach's α = .59), respectively. The rest are filler items.

Statistical Analysis

Participants' characteristics were calculated at baseline using means and standard deviations. Following the *Consolidated Standards of Reporting Trials* (CONSORT), analyses were performed according to an intention-to-treat principle using all available data from all randomized participants (Chambless & Hollon, 1998). To accommodate between- and within-effects considering missing data and unequal numbers of observations, we fitted linear mixed models to the longitudinal measures of outcomes (Singer & Willett, 2003). At level I, the within-person level, time was specified using the measurement points: the baseline measurement (4-6 months after injury) was defined as 0, the post-measurement (12 months after injury) was defined as 1, and follow-up measurement (18 months after injury) was defined as 2. By doing so, the intercept could be interpreted as an outcome score at the baseline measurement. At level II, the between-person level, treatment conditions were specified as 0 for the CG and 1 for the IG.

The analyses were conducted in R Statistical Language with the R-package *nlme* (Pinheiro et al., 2021) using full maximum likelihood estimation. The normal distribution of the outcome variables was confirmed by inspecting the residual diagnostics of the fitted models.

For each outcome variable, the analysis proceeds through different steps according to the techniques described in Tasca and Gallop (2009). First, we estimated a null model (intercept only model), which allowed an estimation of the proportion of variation between and within persons in the outcome variable. Then, we examined the within-person trajectories of change across sessions with the first model (unconditional growth model with random intercept). The second model (conditional growth model with random intercept and cross level interaction) allowed us to examine the effect of the study conditions, i.e., to evaluate whether the different study conditions had different rates of change across the three assessments.

Subsequent exploratory models were used to examine whether individual coping abilities and dispositional optimism and pessimism moderated the treatment efficacy of the intervention compared to the CG. For this purpose, we fitted four separate multilevel models for the subscales of the CISS, and two separate models for the two subscales of the LOT-R. The moderator variables were grandmean-centered to create a meaningful null point. All these models include the main effect of (1) the respective moderator, (2) time, (3) condition, (4) all three two-way interactions and (5) the three-way-interaction of the respective moderator variable with condition and time. To show that a variable is a moderator of the treatment success, this variable must not be correlated with the treatment (Beutler et al., 1991). Table 1 shows baseline values of the putative moderators. Our analyses revealed no significant differences between the two groups.

Table 1

Demographics and Clinical Characteristics of Participants

	TAU		IG		*t* (*df*)	χ² (*df*)	*p*
Age					**0.94** (*166.7*)		**0.35**
Mean *(SD)*	50.50	10.35	49.04	10.36			
Gender (%)						**0.58** (*1*)	**0.45**
Female	31	31.00	23	25.00			
Male	69	69.00	69	75.00			
Level of Education (%)						**0.70** (*2*)	**0.71**
No high school diploma	70	70.70	64	69.56			
High-School and above	25	25.25	26	28.26			
Others	4	4.05	2	2.17			
Missing values	1		0				
Annual Income at Baseline						**4.34** (*4*)	**0.36**
Up to CHF 40 000	6	6.19	7	8.14			
Up to CHF 60 000	21	21.65	16	18.60			
Up to CHF 80 000	30	30.92	30	34.88			
Up to CHF 100 000	27	27.84	15	17.44			
Over CHF 100 000	13	13.40	18	20.93			
Missing values	3		14				
Occupational Classification (%)						**1.31** (*1*)	**0.25**
Blue-collar-worker	60	60.60	64	69.57			
White-collar-worker	39	39.39	28	30.43			
Missing values	1		0				
Accident Type (%)						**1.28** (*1*)	**0.26**
Recreational	70	76.09	60	67.42			
Work-related	22	23.91	29	32.58			
Missing values	8		3				
Outcome Variables							
Well-being (BWQ) at baseline							
Life Satisfaction					**1.28** (*176*)		**0.20**
Mean *(SD)*	4.58	0.70	4.43	0.80			

	TAU Mean	TAU SD	IG Mean	IG SD	t (df)	p
Negative Feelings					**0.35** *(160)*	**0.72**
Mean *(SD)*	2.68	0.83	2.73	0.83		
Job Satisfaction (AKZ) at baseline					**0.18** *(172.*	**0.86**
Mean *(SD)*	4.73	1.18	4.70	1.19	*4)*	
Family-related Satisfaction (IRES) at baseline					**0.28** *(182)*	**0.78**
Mean *(SD)*	3.16	0.92	3.12	0.87		
Health-related Satisfaction (IRES) at baseline					**0.64** *(183.7)*	**0.52**
Mean *(SD)*	4.13	0.70	4.07	0.61		

Moderator Variables

Coping Abilities (CISS) at baseline

	TAU Mean	TAU SD	IG Mean	IG SD	t (df)	p
Task-orientated					**0.50** *(181.7)*	**0.62**
Mean *(SD)*	3.77	0.59	3.82	0.55		
Emotion-orientated					**-0.96** *(178.6)*	**0.34**
Mean *(SD)*	2.45	0.75	2.556	0.67		
Avoidance					**0.631** *(177.6)*	**0.53**
Mean *(SD)*	2.51	0.68	2.44	0.72		
Distraction					**0.54** *(181)*	**0.59**
Mean *(SD)*	1.96	0.77	1.90	0.75		
Social Diversion					**0.43** *(180.9)*	**0.67**
Mean *(SD)*	3.06	0.87	3.01	0.90		
Optimism (LOT-R) at baseline						
Optimism					**1.28** *(177.9)*	**0.20**
Mean *(SD)*	8.92	2.14	8.50	2.33		
Pessimism					**-1.05** *(179.2)*	**0.30**
Mean *(SD)*	4.72	2.23	5.08	2.39		

Note. TAU = treatment as usual (*n* = 100), *IG* = intervention group (*n* = 92), comparison between TAU- and IG are performed two-sided Welch's t-test for continuous data and Yates continuity correction for the chi square test for categorical variables.

In case of a significant three-way-interaction, we plotted the adjusted means of the subgroups to facilitate the interpretation of this effect. To guide our interpretation, we further conducted simple slope analyses to test which slope differed significantly from zero (Preacher et al., 2006). We also conducted post-hoc-tests of the mean-differences of these interactions for Time x Condition one standard deviation above (i.e., high level) and below (i.e., low level) the mean of the moderator, using the R package *phia* (De Rosario-Marinez et al., 2015). These follow-up analyses serve to illustrate the specific nature of the interactions.

We estimated all models as linear because of the sparse number of measurement points (Singer & Willett, 2003). The slopes in all models were fixed, as no model yielded significantly lower global fit indices when including random slopes. As a global effect size, we calculated Nagelkerke's pseudo-R^2 statistics, and as local effect size we calculated Cohens' *d*.

Results

The majority of the 192 participants of the final sample were male *(n =* 138; 71.9%) with a mean age of 49.8 years (*SD =* 10.4). Of the randomized participants whose screening results suggested a mental health counseling (*n =* 75), 42 participants (56%) refused to participate. The remaining 33 participants received an average of 2.23 (*SD =* 6.94) mental-health counselling sessions of approximately 50 minutes' duration per session. Of the 35 participants whose screening results indicated a work-related high-risk profile, 30 participants (85.7%) received one session of occupational counselling and, if the employer agreed, a structured observational analysis of the workplace. We found no significant association with any sociodemographic variables or non-compliance. Figure 1 shows a CONSORT-diagram of the flow of participants throughout the study.

Figure 1

CONSORT Flowchart of Participants
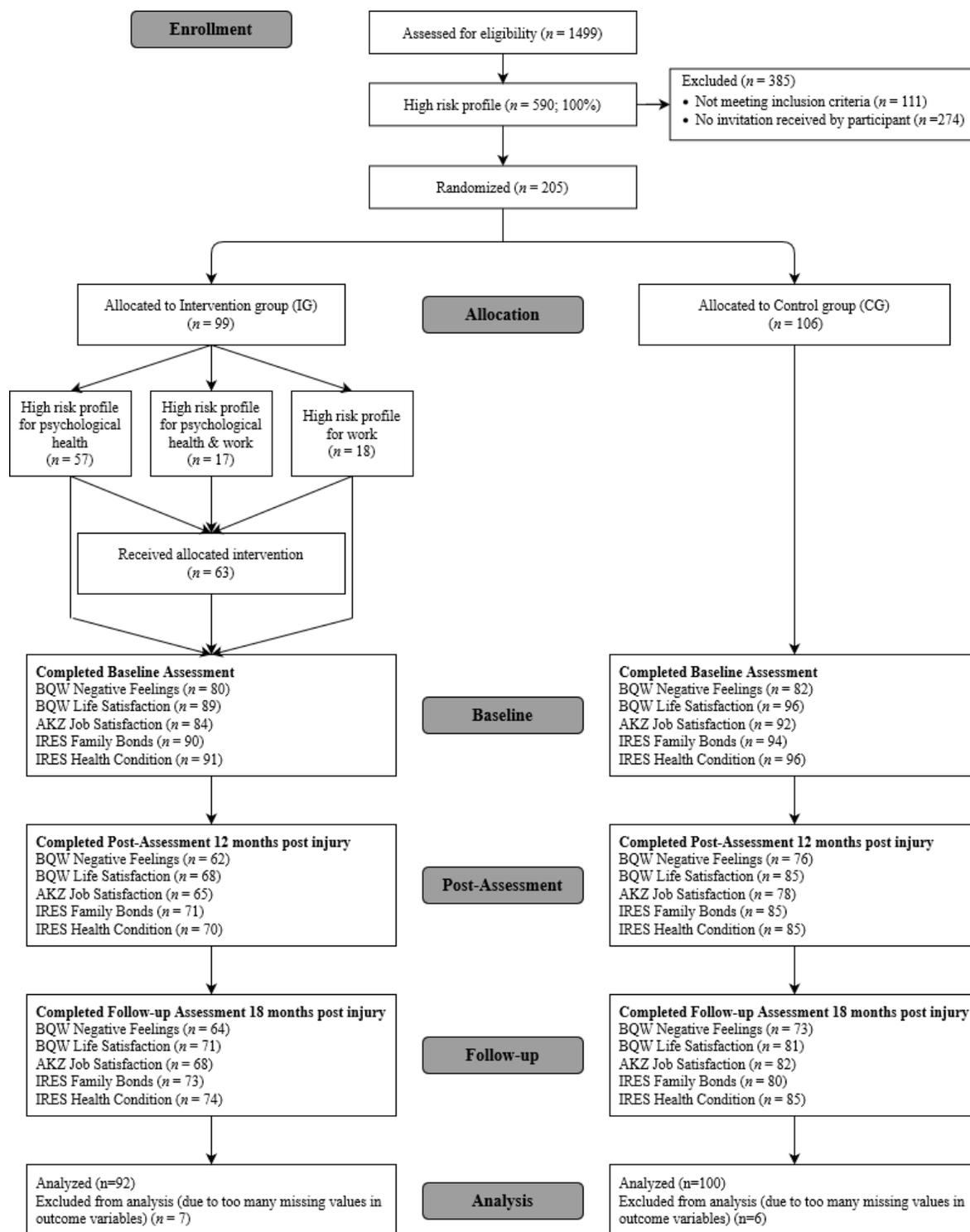
Of the five evaluated coping styles, only social diversion and emotion-oriented coping were significant moderators of treatment success. We found that social diversion moderated the effect of treatment condition on changes in life satisfaction (b = -0.10, SE = .048, p = .045) (see Table 2). This model explained 52% of the variance (Pseudo R^2, adjusted by Nagelkerke).

Table 2

Results of the Multilevel Models for Change in Life Satisfaction across Time and Conditions and Significant Moderators

		Model 1 Unconditional Growth Model			Model 2 Conditional Growth Model (Cross Level Interaction)			Model 3 Conditional Growth Model (Treatment and Moderator)		
Fixed Effects		*B*	*SE B*	*t*	*B*	*SE B*	*t*	*B*	*SE B*	*t*
Intercept	γ_{00}	4.48	0.06	81.37***	4.54	0.08	59.39***	4.54	0.08	58.45**
Treatment	γ_{01}				-0.11	0.11	-1.03	-0.11	0.11	-1.01
Time	γ_{10}	-0.01	0.02	-0.56	-0.05	0.03	-1.70	-0.05	0.09	-1.83[†]
Social Diversion	γ_{02}							0.10	0.09	1.12
Time x Treatment	γ_{11}				0.08	0.04	1.88[†]	0.09	0.03	2.02*
Time x Diversion	γ_{12}							0.03	0.04	0.91
Treatment x Diversion	γ_{03}							0.17	0.03	1.32
Time x Treatment x	γ_{13}							-0.10	0.13	-2.01*
Random Effects										
Intercept	σ^2_0	0.44	[0.35 - 0.55]		0.44	[0.35 - 0.55]		0.44	[0.35 - 0.56]	
Residual	$\sigma^2\varepsilon$	0.15	[0.13 - 0.18]		0.15	[0.13 - 0.18]		0.14	[0.11 - 0.17]	
Model Fit		**Dev**	**AIC**	**BIC**	**Dev**	**AIC**	**BIC**	**Dev**	**AIC**	**BIC**
		865.0	873.0	889.84	861.4	873.4	898.5	827.6	849.6	895.5

Note. $n_1 = 490$, $n_2 = 191$; Model 3a: $n_1 = 183$, $n_2 = 477$; 95% Confidence Intervals in parentheses; *p < 0.05; **p < 0.01; ***p < 0.001; †p < 0.07; Dev= -2*Log Likelihood (LL) of the model; AIC = Akaike information criterion; BIC = Bayesian information criterion.

According to the simple slopes analyses, only lower levels of social diversion predicted an increase in life satisfaction for participants in the IG ($b = 0.10$, $t(289) = 2.62$, $p < .001$). As can be seen in Figure 2, the simple slopes for participants in the CG were not significant ($b = -0.76$, $t(289) = 1.80$, $p = .073$). Post-hoc contrast analyses revealed significant mean differences between the CG and the IG from T0 to T1 ($\chi 2(1) = 8.11$, $p < .05$), and from T0 to T2 ($\chi 2(1) = 7.99$, $p < .05$) for low social diversion scores. Cohens' d for the analysis from T0 to T2 was $d = -0.22$ in the CG and $d = 0.26$ in the IG, which correspond to small effects.

Figure 2

Moderating Effect of Social Diversion on Changes in Life Satisfaction for CG and IG
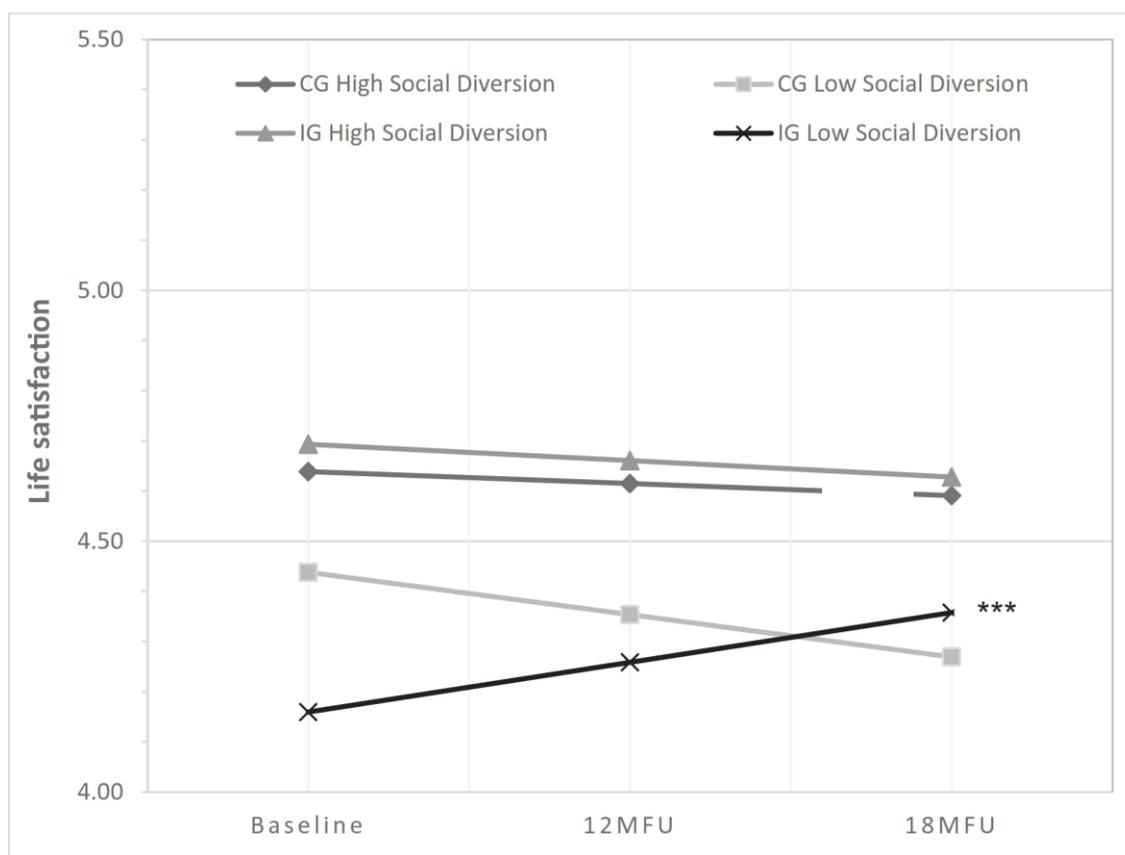
Note. *** $= p < 0.001$, the scale of the y-axis starts with 4.0 and ends with 5.5.

Furthermore, we found that social diversion moderated the effect of treatment condition on changes in job satisfaction (γ = -0.23, SE = .099, p = .022) (see Table 2). This model explained 30% of the variance (Nagelkerke's pseudo-R^2 statistics). According to the simple slopes analyses, lower levels of social diversion predicted a decrease in job satisfaction for participants in the CG (b = -0.27, t(456) = -3.06, p = .002). All three other simple slopes did not significantly differ from 0 (see Figure 3). Post-hoc contrast analyses revealed no significant mean differences between the CG and the IG for different measurement points in relation to high or low social diversion (Tables 3 and 4).

Table 3

Results of the Multilevel Models for Change on Negative Feelings across Time and Conditions and Significant Moderators

		Model 1 Unconditional Growth Model			Model 2 Conditional Growth Model (Cross Level Interaction)			Model 3a Conditional Growth Model (Treatment and Moderator)			Model 3b Conditional Growth Model (Treatment and Moderator)		
Fixed Effects		*B*	*SE B*	*t*	*B*	*SE B*		*B*	*SE B*	*t*	*B*	*SE B*	*t*
Intercept	γ_{00}	2.71	0.06	42.07**	2.70	0.09	30.20***	2.73	0.09	31.14**	2.71	0.09	30.46**
Treatment	γ_{01}				0.02	0.13	0.13	-0.04	0.12	-0.34	-0.01	0.13	-0.09
Time	γ_{10}	-0.09	0.03	-3.46***	-	0.04	-0.67	-0.02	0.04	-0.69	-0.03	0.04	-0.91
Emotion-Oriented	γ_{02}							0.40	0.12	3.41***			
Optimism	γ_{02}										-0.09	0.04	-2.08*
Time x Treatment	γ_{11}				-	0.05	-2.69***	-0.14	0.05	-2.54**	-0.13	0.05	-2.59**
Time x Emotion-Oriented	γ_{12}							0.08	0.05	1.72			
Time x Optimism	γ_{12}										-0.04	0.02	-2.52*
Treatment x Emotion	γ_{03}							0.12	0.18	0.70			
Treatment x Optimism	γ_{03}										-0.06	0.06	-1.12
Time x Treatment x	γ_{13}							-0.18	0.08	-2.36*			
Time x Treatment x	γ_{13}										0.07	0.02	3.05***
Random Effects													
Intercept	σ^2_0	0.56	[0.44 - 0.71]		0.56	[0.44 -0.71]		0.47	[0.37 - 0.61]		0.50	[0.39 -0.65]	
Residual	σ^2_ε	0.19	[0.16 - 0.23]		0.18	[0.15 - 0.22]		0.18	[0.15 - 0.22]		0.17	[0.14 - 0.20]	
Model Fit		**Dev**	**AIC**	**BIC**	**Dev**	**AIC**	**BIC**	**Dev**	**AIC**	**BIC**	**Dev**	**AIC**	**BIC**
		883.2	891.5	907.8	875.	887.4	911.9	817.7	837.7	878.2	818.9	832.9	861.2

Note. $n_1 = 437$, $n_2 = 182$; Model 3a: $n_1 = 422$, $n_2 = 174$; Model 3b: $n_1 = 423$ $n_2 = 17395\%$ Confidence Intervals in parentheses; *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$; †$p < 0.07$; *Dev* = -2 * Log Likelihood (LL) of the model; *AIC* = Akaike information criterion*; BIC* = Bayesian information criterion.

Table 4

Results of the Multilevel Models for Change on Job Satisfaction across Time and Conditions and Significant Moderators

		Model 1 Unconditional Growth Model			Model 2 Conditional Growth Model (Cross Level Interaction)			Model 3a Conditional Growth Model (Treatment and Moderator)			Model 3b Conditional Growth Model (Treatment and Moderator)		
Fixed Effects		B	$SE\ B$	t	B	$SE\ B$	t	B	$SE\ B$	t	B	$SE\ B$	t
Intercept	γ_{00}	4.71	0.08	56.28***	4.73	0.12	40.90***	4.74	0.12	39.85***	4.75	0.12	41.21***
Treatment	γ_{01}				-0.05	0.17	-1.00	-0.05	0.17	-0.26	-0.02	0.17	-0.14
Time	γ_{10}	-0.05	0.04	-1.13	-0.06	0.06	-0.32	-0.07	0.06	-1.09	-0.08	0.06	-1.26
Diversion	γ_{02}							-0.23	0.14	-1.66			
Optimism	γ_{02}										-0.03	0.05	-0.60
Time x Treatment	γ_{11}				0.02	0.09	0.25	0.02	0.09	0.26	0.04	0.09	0.45
Time x Diversion	γ_{12}							0.23	0.07	3.40***			
Time x Optimism	γ_{12}										0.07	0.03	2.46**
Treatment x Diversion	γ_{03}							0.37	0.19	1.89†			
Treatment x Optimism	γ_{03}										0.23	0.07	3.18***
Time x Treatment x Diversion	γ_{13}							-0.23	0.10	-2.31*			
Time x Treatment x Optimism	γ_{13}										-0.10	0.04	-2.49***

Random Effects												
Intercept	σ^2_0	0.75	[0.57 - 1.00]		0.75	[0.57 - 1.00]		0.78	[0.59 - 1.00]		0.67	[0.50 - 0.90]
Residual	$\sigma^2\varepsilon$	0.58	[0.49 - 0.68]		0.58	[0.49 - 0.68]		0.56	[0.47 - 0.66]		0.57	[0.48 - 0.67]

Model Fit	Dev	AIC	BIC	Dev	AIC	BIC	Dev	AIC	BIC	Dev	AIC	BIC
	1336.2	1344.2	1360.8	1336.1	1348.1	1373.0	1293.3	1313.3	1354.6	1271.7	1291.7	1332.9

Note. $n_1 = 469$, $n_2 = 184$; Model 3a: $n_1 = 422$, $n_2 = 174$; Model 3b: $n_1 = 454$ $n_2 = 177$, 95% Confidence Intervals in parentheses; *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$; †$p < 0.07$; *Dev* = -2 * Log Likelihood (LL) of the model; *AIC* = Akaike information criterion; *BIC* = Bayesian information criterion

Figure 3

*Moderating Effect of Social Diversion on Changes in Job Satisfaction for CG and IG*
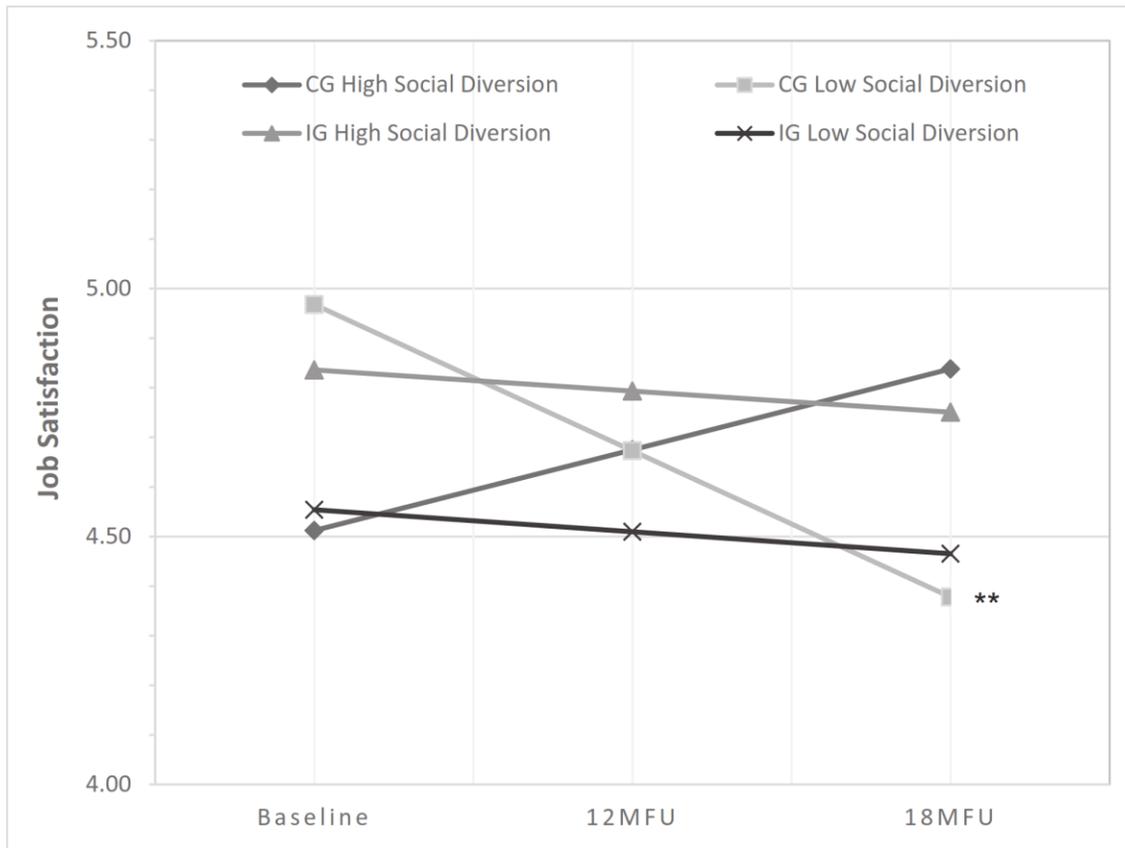
Note. ** = p < 0.01; the scale of the y-axis starts with 4.0 and ends with 5.5.

We also found that an emotion-oriented coping style moderated the effect of treatment condition on changes in negative feelings (b = -0.02, SE = .080, p = .025) (see Table 2). This model explained 54% of the variance (Nagelkerke's pseudo-R^2 statistics). According to the simple slopes analyses, levels of an emotion-oriented coping style predicted a decrease in negative feelings over time for participants in the IG (b = -0.08, $t(253)$ = -2.50, p = .013) (see Figure 4). All other simple slopes were not significant. Post-hoc contrast analyses revealed significant mean differences between the CG and the IG from T0 to T1 ($\chi2(1)$ = 11.51, $p < .001$),

and for T0 to T2 ($\chi 2$(1) = 12.19, $p < .001$) for high emotions-oriented scores. Effect sizes for T0 to T1 were Cohen's $d = .14$ in the CG, and $d = .64$ in the IG, which correspond to small (CG) and medium (IG) effects.

Figure 4

*Moderating Effect of Emotion-oriented Coping on Changes in Negative Feelings for CG and IG*
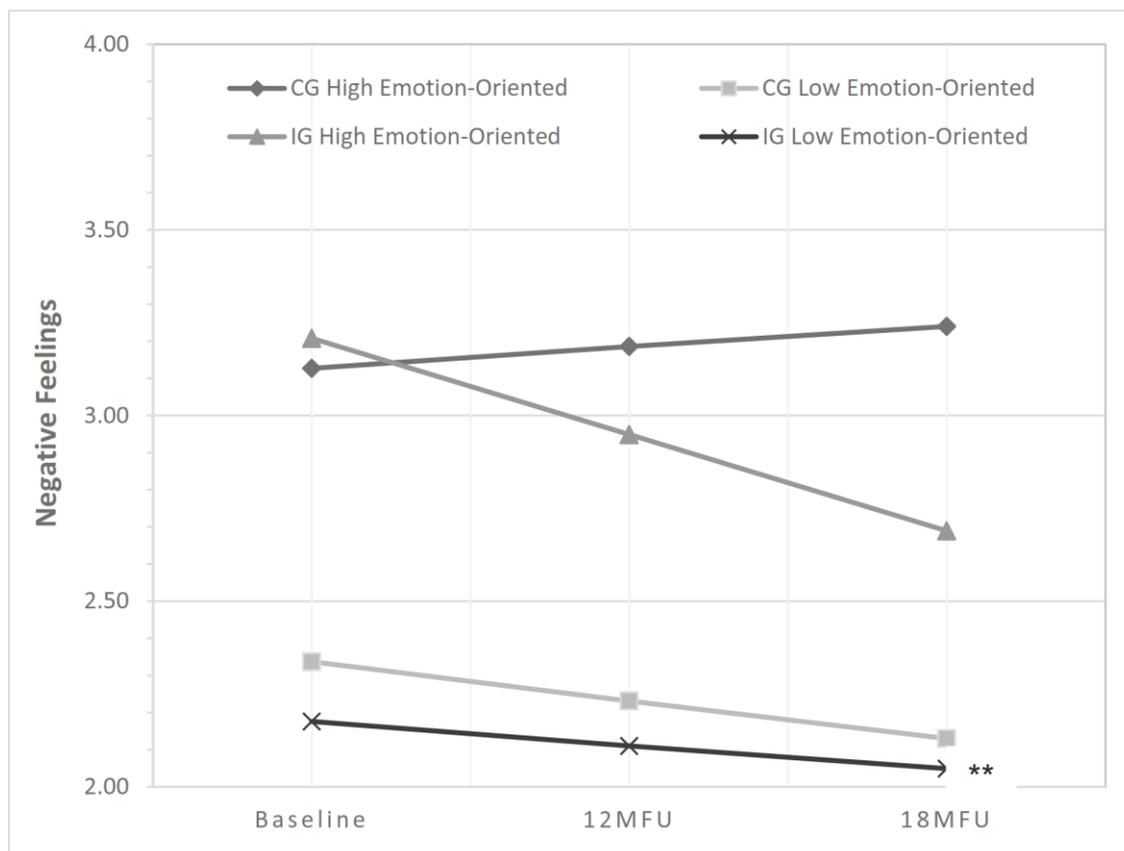
Note. ** $= p < 0.01$; the scale of the y-axis starts with 2.0 and ends with 4.0.

Next, we evaluated if optimism or pessimism had a moderating effect on different aspects of subjective well-being in the IG compared to the CG. For pessimism, we found no significant moderator effect on all five evaluated aspects of well-being. However, we found that dispositional optimism moderated the effect of treatment condition on changes in negative feelings ($b = 0.07$, $SE = .024$, $p = .003$) (see Table 2). This model explained 55% of the variance (Nagelkerke's pseudo-R^2 statistics). According to the simple slopes analyses, lower levels of

optimism 1 *SD* below the mean predicted a decrease in negative feelings for participants in the

IG (b = -0.23, t(244) = -2.41, p = .017). For the CG, higher levels of optimism predicted a

decrease in negative feelings (b = -0.12, t(244) = -4.01, p < .001). All other simple slopes did not

significantly differ from 0 (see Figure 5). Post-hoc contrast analyses revealed significant mean

differences between the CG and the IG from T0 to T1 ($\chi 2$(1) = 8.64, p < .01), and from T0 to T2

($\chi 2$(1) = 14.77, p < .001) for low optimism values. Cohens' d for T0 to T1 was d = 0.02 in the

CG, and d = 0.48 in the IG, which correspond to small effects.

Figure 5

Moderating Effect of Dispositional Optimism on Changes in Negative Feelings for CG and IG
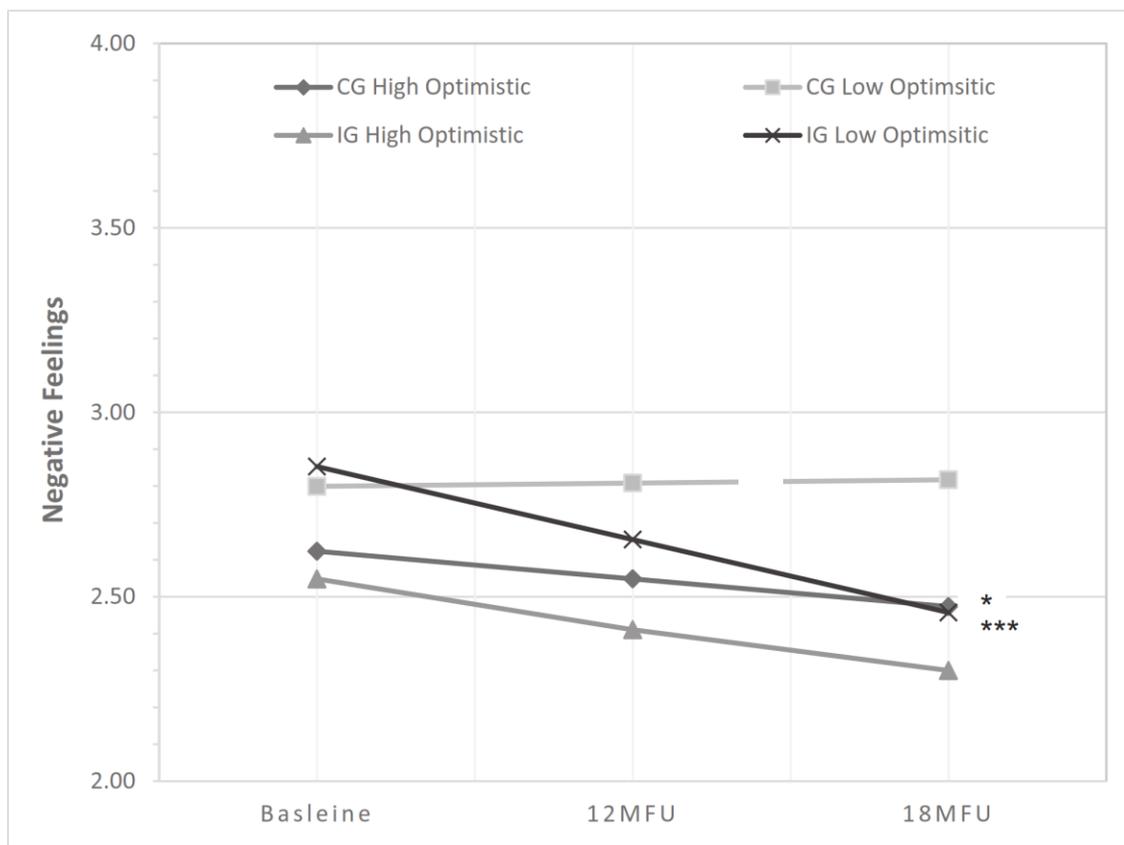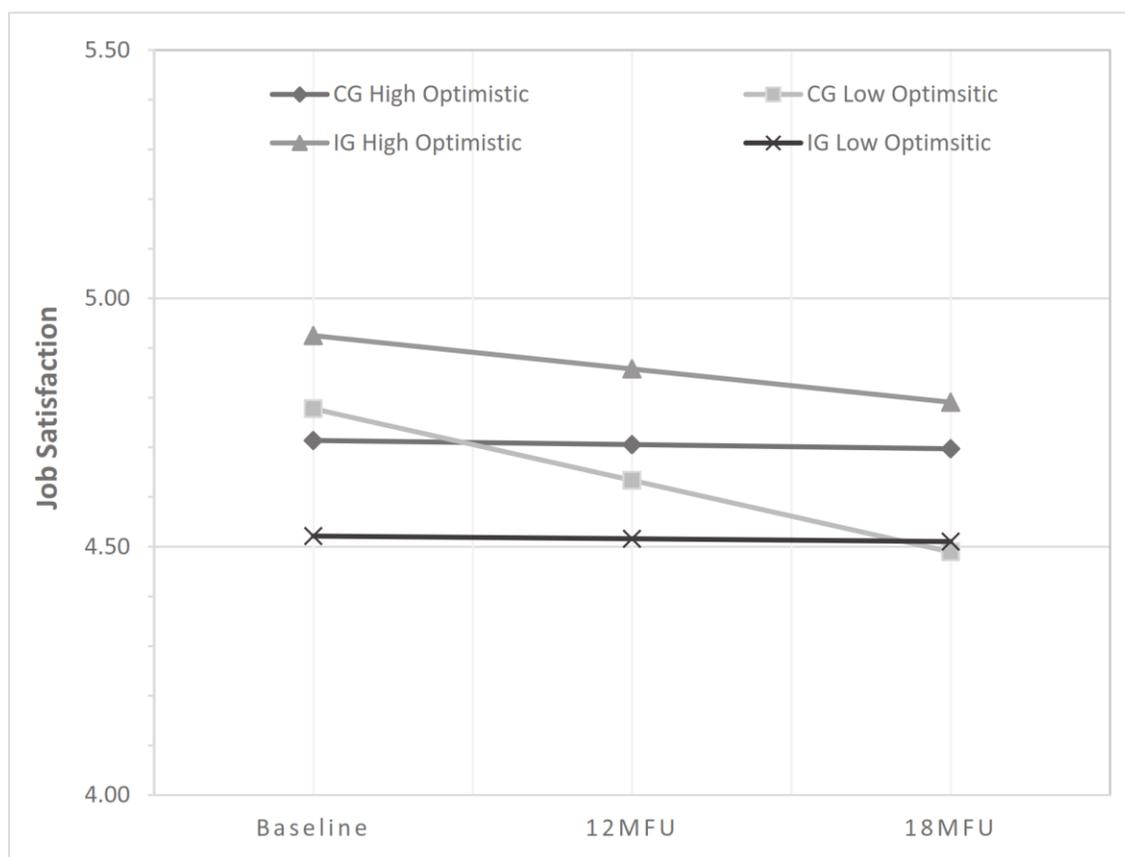

Note. *** $= p < 0.001$; * $= p < 0.05$; the scale of the y-axis starts with 2.0 and ends with 4.0.

We also found that dispositional optimism moderated the effect of treatment condition on changes in job satisfaction ($b = $ -0.10, $SE = .040$, $p = .014$) (see Table 2). Simple slope analyses revealed that no simple slope significantly differed from 0 (see Figure 6). In terms of within-group effects, post-hoc contrast analyses detected no significant differences between the CG and the IG for the different measurement points in relation to levels of optimism.

Figure 6

Moderating Effect of Dispositional Optimism on Changes in Job Satisfaction for CG and

IG

Note. The scale of the y-axis starts with 4.0 and ends with 5.5.

Discussion

In this study we conducted exploratory analyses to examine moderators of treatment outcome of

an RCT in which a combination of conventional case management and highly tailored

counselling was compared to conventional case management only. The results of these analyses

revealed that dispositional optimism and the emotion-oriented coping and social diversion

coping styles moderated the treatment efficacy of three different aspects of well-being, namely life satisfaction, job satisfaction, and negative feelings.

Social Diversion

Concerning the coping style social conversion, we found that participants in the IG with low levels of social diversion showed improvements in life satisfaction, whereas participants in the CG showed a statistical trend ($p = .07$) towards decreased life satisfaction. Further inspection of the interaction plots revealed a stable trajectory for participants with high levels of social diversion regardless of the experimental condition. We also found that participants in the CG with low levels of social diversion showed a significant decrease in job satisfaction over time.

Seeking social distraction through a supportive, emphatic social network could be a feasible way to cope with distress (Folkman, 2013; Folkman & et al, 1986; Tough et al., 2017; Zinman et al., 2014). Our intervention, which explicitly targeted resource activation, i.e., a focus on strengths and potentials of participants, might have contributed to the discovery and use of their available social resources (Flückiger et al., 2010). Accordingly, the social distraction that a person's social network can provide, could be seen as a reactivated personal resource for seeking and activating social support (Hatchett & Park, 2004). This activated and perceived social support may in turn have led to the observed improvement in life satisfaction and buffering of the decrease in job satisfaction. This post-hoc explanation is in line with numerous findings on the preventative effect of social support on health-related quality of life and well-being for individuals with health-related adversities (Brands et al., 2014; Kendrick, Kelllezi, et al., 2017; Livneh & Martz, 2014; Tough et al., 2017). In the same manner, research has shown that coping skills of injured persons can change over the course of a cognitive-behavioral-oriented treatment (e.g., Anson & Ponsford, 2006). Zinman et al. (2014) even report an increase in the use of the

social diversion coping style after an outpatient reintegration program for people with spinal cord injury.

Our findings may have implications for clinical practice, since the results suggest that an intervention including resource activation and goal-oriented attempts to foster social resources may help reducing the extent to which physical injury results in decreased psychological well-being.

Emotion-oriented Coping

Concerning emotion-oriented coping, we found that participants in the IG with low levels of emotion-oriented coping showed a decrease in negative feelings. Moreover, post-hoc contrast analyses revealed that IG-participants with high levels of emotion-oriented coping showed lesser negative feelings at both the post and the follow-up assessment compared to CG-participants with high levels of emotion-oriented coping (Figure 4). Participants in the CG with high emotion-oriented coping even showed a statistical trend towards an increase in negative feelings over time.

Emotion-oriented coping is focused on a reduction and the management of the intensity of distressing emotions elicited by an adverse event (Folkman & et al, 1986). Emotion-oriented coping strategies are mostly seen as a short-term adaptive alternative to other coping styles, for example if emotional responses are too intense to solve a problem or if a situation cannot be changed and goal-oriented coping therefore is not possible (Folkman & et al, 1986). Even though emotion-oriented coping does not have to be exclusively maladaptive, it does not solve the source of the emotional distress. Thus, offering counselling to injured workers who use emotion-oriented coping might help guide them towards more positive and helpful forms of emotion-oriented coping. We assume that the counselled participants have learned more flexible ways of coping, including emotion-oriented coping. Indeed, a closer inspection of the treatment plans for

the counselled participants revealed that the development of adaptive coping strategies and their flexible use was explicitly stated as a main treatment goal in most cases. This assumption is in line with several findings on cognitive-behavioral oriented interventions which were shown to be effective in increasing adaptive coping strategies (e.g., Anson & Ponsford, 2006; Hanks et al., 2012; Zinman et al., 2014).

Our findings may have implications for clinical practice. To support the post-injury adjustment process, it may be beneficial to help individuals build a broader coping repertoire and encourage a more flexible use of adaptive coping styles. Thus, psychoeducation regarding different coping styles, establishing the promotion of adaptive coping styles as an explicit therapeutic goal, and compatible cognitive-behavioral therapeutic interventions could be feasible first steps to improve the experience of self-efficacy in injured workers. Additionally, screening for emotion-oriented coping, and if present, guiding patients towards adaptive, positive emotion-oriented coping might be helpful.

Dispositional Optimism

Finally, we found that IG-participants with low levels of dispositional optimism, and CG-participants with high levels of dispositional optimism both showed a significant decrease in negative feelings. Moreover, post-hoc contrast analyses revealed significant between group differences for people with low levels of dispositional optimism: IG-participants with low levels of optimism showed fewer negative feelings at the post and the follow-up assessment than CG-participants with low levels of optimism (Figure 5).

This difference may suggest that the intervention was able to compensate for the lack of optimism. In line with this assumption, Carver and colleagues (Carver et al., 2010; Carver & Scheier, 2014) have postulated, cognitive restructuring techniques contribute to the establishment

of a more optimistic view in psychotherapy settings. A closer look at the counseling techniques used in our intervention revealed that all counselors applied cognitive restructuring techniques. Thus, challenging irrational and maladaptive beliefs and introducing more adaptive thinking patterns might be helpful in supporting post-injury adjustment processes. Also, these results point to a confirmation of the findings of previous studies whereby optimism has a positive effect on different aspects of well-being in individuals facing health-related adversities (Carver et al., 2010; Skogstad et al., 2014; Vassend et al., 2011).

Limitations and Strengths

One limitation of our study is, that we found only few differential treatment effects. Of the seven potential moderator variables, only three contributed significantly to the explanation of variance in our models. This may be partly due to the rather small sample of 192 participants and the resulting limited statistical power. Although our sample was larger than those of other rehabilitation studies (e.g., Giummarra et al., 2018; Stamenova & Levine, 2019; Tornås et al., 2019), it was still rather modest considering that we conducted moderation analyses in a multilevel setting. Therefore, our results should be considered as hypothesis-generating findings that can be further investigated in future studies.

A strength of this study is its high methodologic quality as it met several Cochrane collaboration criteria including randomization concealment, using an intention-to-treat principle, a loss to follow-up lesser than 50%, and a trial assessor who was blinded from the data collection process. Moreover, the study was monitored by an external assessment center, and we employed a long follow-up period of one and a half years post injury. In contrast to previous rehabilitation intervention studies (e.g., De Silva et al., 2009; Giummarra et al., 2018; Guest et al., 2015), we applied more robust statistical methods, which takes the hierarchical structure in the data into

consideration and improves the handling of missing data (Singer & Willett, 2003; Tasca & Gallop, 2009).

Finally, our findings add to the growing evidence that low-threshold interventions for injured persons may be useful in preventing psychological sequelae. Additionally, we found support for the importance of considering the interaction between participant characteristics and treatment for the prediction of outcomes. Our findings suggest that pretreatment coping abilities and dispositional optimism may help predict which individuals will benefit most from counselling. Such predisposing factors should be assessed through screening and incorporated in treatment plans. However, further RCTs are needed to replicate our findings and to investigate possible mechanisms of patient characteristics on treatment efficacy in injury rehabilitation.

Implications for clinical practice

In our study, we found that injured workers low in social diversion, high in emotion-oriented coping and low in optimism benefited the most from our counselling intervention. Based on further inspection of the participants' individual treatment plans, we assume that different treatment components of our tailored intervention had an influence on these observed effects. First, a strong focus on participants' resources, strengths and potentials may have contributed to the reactivation of the participants' perceived social support (Flückiger et al., 2010). Additionally, psychoeducation on coping styles, the promotion of adaptive coping styles as an explicit therapeutic goal, and guiding patients towards adaptive emotion-oriented coping might be helpful elements to use when counselling injured workers (Zinman et al., 2014). Finally, challenging maladaptive beliefs through cognitive restructuring techniques might have contributed to a more optimistic outlook and to the establishment of a more optimistic view in

psychotherapy settings (Carver et al., 2010). Although these findings need confirmation, our results provide preliminary evidence for differential treatment effects in injury rehabilitation, which could both guide further research efforts and support treatment decisions to facilitate patient's adjustment to accidental injuries.

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Author contributions

This study was conceptualized by HJZ, VS and UHR but all authors contributed equally to the final methodology. HJZ, VS, UHR recruited the participants. VS and HJZ supervised the interventions. SA performed data collection and analysis. SA, HJZ and JH interpreted the analyses. SA and JH drafted the manuscript. All authors significantly contributed to the writing of the manuscript.

References

Abegglen, S., Hoffmann-Richter, U., Schade, V., & Znoj, H. J. (2017). Work and Health
Questionnaire (WHQ): A Screening Tool for Identifying Injured Workers at Risk for a
Complicated Rehabilitation. *Journal of Occupational Rehabilitation*, *27*(2), 268–283.
https://doi.org/10.1007/s10926-016-9654-1

Anson, K., & Ponsford, J. (2006). Coping and emotional adjustment following traumatic brain
injury. *Journal of Head Trauma Rehabilitation*, *21*(3), 248–259.
https://doi.org/10.1097/00001199-200605000-00005

Archer, T., Rapp-Ricciardi, M., Archer, T., & Rapp-Ricciardi, M. (2019). Stress, Affective
Status and Neurodegenerative Onslaughts. *Contemporary Clinical Neuroscience*, 41–58.
https://doi.org/10.1007/978-3-319-90065-0_3

Beutler, L. E., Mohr, D. C., Grawe, K., Engle, D., & MacDonald, R. (1991). Looking for
differential treatment effects: Cross-cultural predictors of differential psychotherapy
efficacy. *Journal of Psychotherapy Integration*, *1*(2), 121–141.
https://www.researchgate.net/profile/David-
Mohr/publication/224071391_Looking_for_differential_treatment_effects_Cross-
cultural_predictors_of_differential_psychotherapy_efficacy/links/59d38cbf4585150177f9
6101/Looking-for-differential-treatment-effects-Cro

Brands, I., Köhler, S., Stapert, S., Wade, D., & Van Heugten, C. (2014). Influence of self-
efficacy and coping on quality of life and social participation after acquired brain injury:
A 1-year follow-up study. *Archives of Physical Medicine and Rehabilitation*, *95*(12),
2327–2334. https://doi.org/10.1016/j.apmr.2014.06.006

Bührlen, B., Gerdes, N., & Jäckel, W. H. (2005). Entwicklung und psychometrische Testung

    eines Patientenfragebogens für die medizinische Rehabilitation (IRES-3). *Die*

    Rehabilitation, *44*(02), 63–74. https://doi.org/10.1055/S-2004-834687

Bültmann, U., Sherson, D., Olsen, J., Hansen, C. L., Lund, T., & Kilsgaard, J. (2009).

    Coordinated and tailored work rehabilitation: A randomized controlled trial with

    economic evaluation undertaken with workers on sick leave due to musculoskeletal

    disorders. *Journal of Occupational Rehabilitation*, *19*(1), 81–93.

    https://doi.org/10.1007/S10926-009-9162-7/TABLES/7

Cancelliere, C., Donovan, J., Stochkendahl, M. J., Biscardi, M., Ammendolia, C., Myburgh, C.,

    & Cassidy, J. D. (2016). Factors affecting return to work after injury or illness: best

    evidence synthesis of systematic reviews. *Undefined*, *24*(1).

    https://doi.org/10.1186/S12998-016-0113-Z

Carver, C. S., & Scheier, M. F. (2014). Dispositional optimism. In *Trends in Cognitive Sciences*

    (Vol. 18, Issue 6, pp. 293–299). Elsevier Ltd. https://doi.org/10.1016/j.tics.2014.02.003

Carver, C. S., Scheier, M. F., & Segerstrom, S. C. (2010). Optimism. In *Clinical Psychology*

    Review (Vol. 30, Issue 7, pp. 879–889). Clin Psychol Rev.

    https://doi.org/10.1016/j.cpr.2010.01.006

Chambless, D. L., & Hollon, S. D. (1998). Defining empirically supported therapies. *Journal of*

    Consulting and Clinical Psychology, *66*(1), 7–18. https://doi.org/10.1037//0022-

    006X.66.1.7

Cullen, K. L., Irvin, E., Collie, A., Clay, F., Gensby, U., Jennings, P. A., Hogg-Johnson, S.,

    Kristman, V., Laberge, M., McKenzie, D., Newnam, S., Palagyi, A., Ruseckaite, R.,

    Sheppard, D. M., Shourie, S., Steenstra, I., Van Eerd, D., & Amick, B. C. (2018).

Effectiveness of Workplace Interventions in Return-to-Work for Musculoskeletal, Pain-Related and Mental Health Conditions: An Update of the Evidence and Messages for Practitioners. *Journal of Occupational Rehabilitation*, *28*(1). https://doi.org/10.1007/S10926-016-9690-X

De Rosario-Marinez, H., Fox, J., & R Core Team. (2015). *phia: Post-Hoc Interaction Analysis* (0.2-4). ttps://cran.r-project.org/web/packages/phia/index.html

De Silva, M., MacLachlan, M., Devane, D., Desmond, D., Gallagher, P., Schnyder, U., Brennan, M., & Patel, V. (2009). Psychosocial interventions for the prevention of disability following traumatic physical injury. In *Cochrane Database of Systematic Reviews* (Vol. 2009, Issue 4). John Wiley and Sons Ltd. https://doi.org/10.1002/14651858.CD006422.pub3

Egli, S. (2018). *Unfall oder Krankheit? Das ist hier die Frage! üAccident or illness? That is the question!]*. https://www.suva.ch/de-ch/news/2018/unfall-oder-krankheit

Flückiger, C., Wüsten, G., Zinbarg, R. E., & Wampold, B. E. (2010). *Resource Activation: Using Clients' Own Strengths in Psychotherapy and Counseling*. Hogrefe Publishing.

Folkman, S. (2013). Stress: Appraisal and Coping. *Encyclopedia of Behavioral Medicine*, 1913–1915. https://doi.org/10.1007/978-1-4419-1005-9_215

Folkman, S., & et al. (1986). Dynamics of a stressful encounter: Cognitive appraisal, coping, and encounter outcomes. *Journal of Personality and Social Psychology*, *50*(5), 992–1003. https://doi.org/10.1037//0022-3514.50.5.992

Giummarra, M. J., Lennox, A., Dali, G., Costa, B., & Gabbe, B. J. (2018). Early psychological interventions for posttraumatic stress, depression and anxiety after traumatic injury: A

systematic review and meta-analysis. In *Clinical Psychology Review* (Vol. 62, pp. 11–

36). Elsevier Inc. https://doi.org/10.1016/j.cpr.2018.05.001

Glaesmer, H., Hoyer, J., Klotsche, J., & Herzberg, P. Y. (2008). Die deutsche Version des Life-

Orientation-Tests (LOT-R) zum dispositionellen Optimismus und Pessimismus.

Zeitschrift Fur Gesundheitspsychologie, *16*(1), 26–31. https://doi.org/10.1026/0943-

8149.16.1.26

Grawe, K. (1997). Research-Informed Psychotherapy. *Psychotherapy Research*, *7*(1), 1–19.

https://doi.org/https://doi.org/10.1080/10503309712331331843

Grawe, K. (2004). *Psychological therapy*. Hogrefe & Juber.

Grob, A., Lüthi, R., Kaiser, F. G., Flammer, A., Mackinnon, A., & Wearing, A. J. (1991). Berner

Fragebogen zum Wohlbefinden Jugendlicher (BFW) [The Bern Subjective Well-Being

Questionnaire for Adolescents (BFW)]. *Diagnostica*, *37*(1), 66–75.

Guest, R., Craig, A., Perry, K. N., Tran, Y., Ephraums, C., Hales, A., Dezarnaulds, A., Crino, R.,

& Middleton, J. (2015). Resilience following spinal cord injury: A prospective controlled

study investigating the influence of the provision of group cognitive behavior therapy

during inpatient rehabilitation. *Rehabilitation Psychology*, *60*(4), 311–321.

https://doi.org/10.1037/rep0000052

Hanks, R. A., Rapport, L. J., Wertheimer, J., & Koviak, C. (2012). Randomized controlled trial

of peer mentoring for individuals with traumatic brain injury and their significant others.

Archives of Physical Medicine and Rehabilitation, *93*(8), 1297–1304.

https://doi.org/10.1016/J.APMR.2012.04.027

Hatchett, G. T., & Park, H. L. (2004). Relationships among optimism, coping styles, psychopathology, and counseling outcome. *Personality and Individual Differences*, *36*(8), 1755–1769. https://doi.org/10.1016/J.PAID.2003.07.014

Hegy, J. K., Abegglen, S., Schade, V., Hoffmann-Richter, U., & Znoj, H. (2021). Effects of a tailored multidisciplinary counselling intervention to support the adjustment process after a traumatic injury: a randomized controlled trial. *Disability and Rehabilitation*, 1–10. https://doi.org/10.1080/09638288.2021.1960442

Higgins, J. E., & Endler, N. S. (1995). Coping, life stress, and psychological and somatic distress: *Https://Doi.Org/10.1002/per.2410090403*, *9*(4), 253–270. https://doi.org/10.1002/PER.2410090403

Kälin, W. (1995). *Deutsche 24-Item Kurzform des Coping Inventory for Stressful Situations (CISS) von NS Endler und JDA Parker. Basierend auf der Übersetzung von N Semmer, F Tschan und V Schade (unveröffentlichter Fragebogen) [German 24-item short form of the coping invento*. Institute of Psychology, University of Bern.

Kendrick, D., Coupland, C., Whitehead, J., Joseph, S., Morriss, R., Dhiman, P., Kellezi, B., Beckett, K., Christie, N., Sleney, J., & Barnes, J. (2017). Psychological morbidity and return to work after injury: Multicentre cohort study. *British Journal of General Practice*, *67*(661), e555–e564. https://doi.org/10.3399/bjgp17X691673

Kendrick, D., Kelllezi, B., Coupland, C., Maula, A., Beckett, K., Morriss, R., Joseph, S., Barnes, J., Sleney, J., & Christie, N. (2017). Psychological morbidity and health-related quality of life after injury: multicentre cohort study. *Quality of Life Research*, *26*(5), 1233–1250. https://doi.org/10.1007/s11136-016-1439-7

Kraemer, H. C., Wilson, G. T., Fairburn, C. G., & Agras, W. S. (2002). Mediators and

    moderators of treatment effects in randomized clinical trials. In *Archives of General*

    Psychiatry (Vol. 59, Issue 10, pp. 877–883). American Medical Association.

    https://doi.org/10.1001/archpsyc.59.10.877

Langford, D. J., Cooper, B., Paul, S., Humphreys, J., Keagy, C., Conley, Y. P., Hammer, M. J.,

    Levine, J. D., Wright, F., Melisko, M., Miaskowski, C., & Dunn, L. B. (2017). Evaluation

    of coping as a mediator of the relationship between stressful life events and cancer-

    related distress. *Health Psychology*, *36*(12), 1147–1160.

    https://doi.org/10.1037/HEA0000524

Lazarus, R. S. (2006). *Stress and Emotion: A New Synthesis*. Springer.

Lazarus, R. S., & Folkman, S. (1984). *Stress, Appraisal, and Coping*. Springer.

Livneh, H., & Martz, E. (2014). Coping strategies and resources as predictors of psychosocial

    adaptation among people with spinal cord injury. *Rehabilitation Psychology*, *59*(3), 329–

    339. https://doi.org/10.1037/a0036733

Marroquín, B., Tennen, H., Stanton, A. L., Marroquín, B., Tennen, H., & Stanton, A. L. (2017).

    Coping, Emotion Regulation, and Well-Being: Intrapersonal and Interpersonal Processes.

    The Happy Mind: Cognitive Contributions to Well-Being, 253–274.

    https://doi.org/10.1007/978-3-319-58763-9_14

Myhren, H., Ekeberg, Ø., & Stokland, O. (2010). Health-related quality of life and return to work

    after critical illness in general intensive care unit patients: A 1-year follow-up study.

    Critical Care Medicine, *38*(7), 1554–1561.

    https://doi.org/10.1097/CCM.0B013E3181E2C8B1

Pinheiro, J., Bates, D., DebRoy, S., Sarkar, D., EISPACK, A., Heisterkamp, S., Van Wilige, B., & Ranke, J. (2021). *nlme: Linear and Nonlinear Mixed Effects Models [software]* (3.1-152). https://cran.r-project.org/web/packages/nlme/index.html

Preacher, K. J., Curran, P. J., & Bauer, D. J. (2006). Computational tools for probing interactions in multiple linear regression, multilevel modeling, and latent curve analysis. *Journal of Educational and Behavioral Statistics*, *31*(4), 437–448. https://doi.org/10.3102/10769986031004437

Rose, A., Rosewilliam, S., & Soundy, A. (2017). Shared decision making within goal setting in rehabilitation settings: A systematic review. In *Patient Education and Counseling* (Vol. 100, Issue 1, pp. 65–75). Elsevier Ireland Ltd. https://doi.org/10.1016/j.pec.2016.07.030

Russell, E., & Kosny, A. (2019). Communication and collaboration among return-to-work stakeholders. *Disability and Rehabilitation*, *41*(22), 2630–2639. https://doi.org/10.1080/09638288.2018.1472815

Scholz, S. M., Andermatt, P., Tobler, B. L., & Spinnler, D. (2016). Work Incapacity and Treatment Costs After Severe Accidents: Standard Versus Intensive Case Management in a 6-Year Randomized Controlled Trial. *Journal of Occupational Rehabilitation*, *26*(3), 319–331. https://doi.org/10.1007/s10926-015-9615-0

Singer, J. D., & Willett, J. B. (2003). *Applied longitudinal data analysis, modeling change and event occurrence*. Oxford University Press.

Skogstad, L., Tøien, K., Hem, E., Ranhoff, A. H., Sandvik, L., & Ekeberg, O. (2014). Psychological distress after physical injury: A one-year follow-up study of conscious hospitalised patients. *Injury*, *45*(1), 289–298. https://doi.org/10.1016/j.injury.2012.10.001

Stamenova, V., & Levine, B. (2019). Effectiveness of goal management training® in improving executive functions: A meta-analysis. In *Neuropsychological Rehabilitation* (Vol. 29, Issue 10, pp. 1569–1599). Routledge. https://doi.org/10.1080/09602011.2018.1438294

Tasca, G. A., & Gallop, R. (2009). Multilevel modeling of longitudinal data for psychotherapy researchers: I. The basics. *Psychotherapy Research : Journal of the Society for Psychotherapy Research*, *19*(4–5), 429–437. https://doi.org/10.1080/10503300802641444

Tecic, T., Schneider, A., Althaus, A., Schmidt, Y., Bierbaum, C., Lefering, R., Mueller, D., Bouillon, B., Janssen, C., Pfaff, H., Erli, H. J., Rangger, C., & Neugebauer, E. A. M. (2011). Early short-term inpatient psychotherapeutic treatment versus continued outpatient psychotherapy on psychosocial outcome: A randomized controlled trial in trauma patients. *Journal of Trauma - Injury, Infection and Critical Care*, *70*(2), 433–441. https://doi.org/10.1097/TA.0b013e3181f024fe

Tein, J.-Y., Sandler, I. N., & Zautra, A. J. (2000). Stressful life events, psychological distress, coping, and parenting of divorced mothers: A longitudinal study. *Journal of Family Psychology*, *14*(1), 27–41. https://doi.org/10.1037//0893-3200.14.1.27

Tornås, S., Stubberud, J., Solbakk, A. K., Evans, J., Schanke, A. K., & Løvstad, M. (2019). Moderators, mediators and nonspecific predictors of outcome after cognitive rehabilitation of executive functions in a randomised controlled trial. *Neuropsychological Rehabilitation*, *29*(6), 844–865. https://doi.org/10.1080/09602011.2017.1338587

Tough, H., Siegrist, J., & Fekete, C. (2017). Social relationships, mental health and wellbeing in physical disability: A systematic review. *BMC Public Health*, *17*(1). https://doi.org/10.1186/s12889-017-4308-6

Vassend, O., Quale, A. J., Røise, O., & Schanke, A. K. (2011). Predicting the long-term impact of acquired severe injuries on functional health status: The role of optimism, emotional distress and pain. *Spinal Cord*, *49*(12), 1193–1197. https://doi.org/10.1038/sc.2011.70

Wade, D. T., & Halligan, P. W. (2004). Do biomedical models of illness make for good healthcare systems? In *British Medical Journal* (Vol. 329, Issue 7479, pp. 1398–1401). BMJ Publishing Group. https://doi.org/10.1136/bmj.329.7479.1398

Wade, D. T., & Halligan, P. W. (2017). The biopsychosocial model of illness: A model whose time has come. In *Clinical Rehabilitation* (Vol. 31, Issue 8, pp. 995–1004). SAGE Publications Ltd. https://doi.org/10.1177/0269215517709890

Zatzick, D., Roy-Byrne, P., Russo, J., Rivara, F., Droesch, R. A., Wagner, A., Dunn, C., Jurkovich, G., Uehara, E., & Katon, W. (2004). A randomized effectiveness trial of stepped collaborative care for acutely injured trauma survivors. *Archives of General Psychiatry*, *61*(5), 498–506. https://doi.org/10.1001/ARCHPSYC.61.5.498

Zinman, A., Digout, N., Bain, P., Haycock, S., Hébert, D., & Hitzig, S. L. (2014). Evaluation of a community reintegration outpatient program service for community-dwelling persons with spinal cord injury. *Rehabilitation Research and Practice*, *2014*. https://doi.org/10.1155/2014/989025

2.3 Article 3: Web-based Self-help Program for Adjustment Problems After an Accident (SelFIT): Protocol for a Randomized Controlled Trial

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Web-based Self-help Program for Adjustment Problems After an Accident

(SelFIT): Protocol for a Randomized Controlled Trial

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Abstract

Background: Accidents and the resulting injuries are one of the world's biggest health care issues often causing long-term effects on psychological and physical health. With regard to psychological consequences, accidents can cause a wide range of burdens including adjustment problems. Although adjustment problems are among the most frequent mental health problems, there are few specific interventions available. The newly developed program *SelFIT* aims to remedy this situation by offering a low-threshold web-based self-help intervention for psychological distress after an accident.

Objective: The overall aim is to evaluate the efficacy and cost-effectiveness of the SelFIT program plus care as usual (CAU) compared to only CAU. Furthermore, the program's user friendliness, acceptance and adherence are assessed. We expect that the use of SelFIT is associated with a greater reduction in psychological distress, greater improvement in mental and physical well-being, and greater cost-effectiveness compared to CAU.

Methods: Adults (n=240) showing adjustment problems due to an accident they experienced between 2 weeks and 2 years before entering the study will be randomized. Participants in the intervention group receive direct access to SelFIT. The control group receives access to the program after 12 weeks. There are 6 measurement points for both groups (baseline as well as after 4, 8, 12, 24 and 36 weeks). The main outcome is a reduction in anxiety, depression and stress symptoms that indicate adjustment problems. Secondary outcomes include well-being, optimism, embitterment, self-esteem, self-efficacy, emotion regulation, pain, costs of health care consumption and productivity loss as well as the program's adherence, acceptance and user-friendliness.

Results: Recruitment began in December 2019 and will continue at least until January 2021 with the option to extend this for another 6 months until July 2021. As of July 2020, 324 people have shown interest in participating and 48 people have given their informed consent.

Conclusions: To the best of our knowledge, this is the first study examining a web-based self-help program designed to treat adjustment problems resulting from an accident. If effective, the program could complement the still limited offer of secondary and tertiary psychological prevention after an accident.

Trial Registration: ClinicalTrials.gov NCT03785912;

https://clinicaltrials.gov/ct2/show/NCT03785912?cond=NCT03785912&draw=2&rank=1

Introduction

Background

The World Health Organization reports tens of millions of accidents annually with about 5 million people dying from the consequences of their injuries [1, 2]. Accidents and resulting injuries are therefore one of the world's biggest health care issues, often causing long-term effects on psychological and physical health. Due to their unpredictability, uncontrollability, suddenness and threat to one's health and integrity, accidents have a high potential for traumatization [3, 4]. Medical treatment immediately after the accident as well as rehabilitation treatments for injured persons have reached a comparatively high standard of care. However, secondary and tertiary prevention of psychological distress are not yet part of the routine care [3]. Furthermore, the need for both physical and psychological rehabilitation is growing and existing services cannot meet the demand [2, 5]. Thus, easily available, flexible and affordable accident rehabilitation and trauma prevention programs are essential to meet the growing demand for and improve existing treatment options in accident rehabilitation. Therefore, we have developed SelFIT, a low-threshold, web-based psychological self-help program for people who experience psychological distress after an accident. This program is now to be evaluated in a randomized controlled trial (RCT).

Psychological Distress and Adjustment Problems After an Accident

Not everybody who suffered an accident develops psychological problems. Nonetheless, when taking into account possible short-term implications such as fear, pain or helplessness, as well as potential long-term consequences like permanent physical damage or financial challenges, the development of psychological problems after an accident is easily understandable [6]. Therefore, experiencing an accident can lead to the development of various psychological

problems and disorders including anxiety, depression and posttraumatic stress disorder [6, 7].
Especially stress related problems such as *adjustment problems* (AjP) are common and frequent among accident victims [8, 9]. By AjP we mean a "maladaptive reaction to a stressful event or ongoing psychosocial difficulties characterized by symptoms of preoccupation with the stressor, recurrent and or distressing thoughts about the stressor, or rumination about its implications" [10, p. 91]. AjP can interfere with everyday functioning, cause a loss of interest in different areas of life and result in an impairment in social or occupational functioning [10]. If persistent, adjustment problems can turn into an adjustment *disorder.* A longitudinal study on adjustment disorder after trauma exposure and major injury conducted in Australia found participants with adjustment disorder 3 months after the trauma were more likely to meet the criteria for a further psychiatric disorder 12 months post-injury [11]. Thus, the existence of an adjustment disorder heightened the risk for developing other, more serious psychological disorders. Moreover, it was found that adjustment disorders becomes chronic in about 20% of all cases and that the presence of an adjustment disorder increases the risk for suicidality [12]. This highlights the importance of developing and implementing interventions to treat psychological distress after trauma exposure like experiencing an accident as early as possible [7, 13] .

Web-based Psychological Interventions

One possibility to implement early interventions for the treatment of psychological distress due to an accident is the development of web-based interventions. Numerous studies have shown that web-based interventions are an effective treatment option for various psychological problems and demographic groups (eg, [14, 15]). There are many different forms of and applications for such interventions. An important distinguishing factor is guidance, that is, the degree of contact with a health care professional given within the program. Unguided or self-

guided programs do not involve any contact with a health care professional whereas guided

programs involve some form of contact or support [16]. Both guided and unguided programs

have proven to be effective treatment options. Yet, the results of several meta-analyses indicate

that guided programs tend to yield greater effects than unguided programs (eg, [16, 17]). This

may be explained by a heightened sense of responsibility in the user when in contact with

another person compared to non-human contact with a machine program [18]. The heightened

sense of responsibility can increase adherence, which in turn can be associated with better patient

results [19, 20]. However, the question arises as to how much and what type of contact is needed

to increase adherence and achieve better treatment effects [20].

In this respect, studies on another form of guidance, namely guidance on demand, are of

particular interest. With the guidance on demand approach, contact with a professional is only

established at a participant's request but is not scheduled or planned per se.

The findings on the effectiveness of guidance on demand are mixed. In a study on the

treatment of tinnitus via the internet, Rheker et al [21] reported that there was no difference

between a program version with guidance on demand and an unguided version. Krieger et al [22]

used the guidance on demand approach in a web-based intervention for increased self-criticism.

Compared to a control group, their results indicate that the treatment with guidance on demand is

effective. The guidance on demand approach was also tested by Kleiboer et al [20]. They

conducted an RCT on the role of support in a web-based problem solving treatment for

depression and anxiety, comparing 5 different forms and degrees of guidance. Participants either

received (1) the program without guidance, or (2) the program with guidance on demand, or (3)

the program with weekly support or (4) no program but non-specific chat or email support or (5)

were allocated to wait-list control group. Concerning program adherence, the guidance on

demand group showed rates comparable to the group with weekly support and significantly higher rates compared to the unguided group. Regarding the treatment effects, however, the guidance on demand group did not show superior effects than the control group [20].

These findings suggest that the guidance on demand approach lies between guided and unguided programs in terms of effectiveness. The approach thus offers a middle way and has the potential to combine some of the most prominent advantages of both guided and unguided treatments: Participants are given the security of knowing that they can turn to a specialist for help and are therefore not completely on their own. However, since no regular contact is scheduled, fewer staff are needed. Thus, programs with on-demand guidance generate lower costs and are less limited to the time and resources of a project's employees than guided programs. This allows for a very flexible use at a self-determined pace. Due to the voluntary nature of the contact with a specialist, the participants' social exposure in a program with guidance-on-demand can be as low as in an unguided program. Programs with guidance on demand also include other advantages of web-based interventions such as easy availability and scalability, i.e., the capacity to increase the number of people who can use the program.

In recent years, various web-based treatment options for adjustment problems and disorders have been developed. One of them is the Trastornos Adaptivos Online, short TAO [23, 24]. The guided program comprises psychoeducative elements, strategies form positive psychology as well as techniques to manage negative emotions and improve problem solving. In addition to the program, participants receive short weekly therapist support via telephone. TAO was well received by both clinicians and patients in a pilot study[24]. The program is currently tested for its effectiveness in an RCT [23].

A further web-based intervention for the treatment of adjustment disorders is the Brief Adjustment Disorder Intervention known as BADI [25, 26]. This program is unguided and consists of four modules, which the participants can process in a self-determined order. The program's theoretical approach is mainly CBT-based but also contains elements of mindfulness as well as findings from research on stress and coping [27]. Preliminary results of an RCT indicate that participants who used the program at least once within a month show a decrease of symptoms of adjustment disorders and an increase in psychological well-being. Nonetheless, there was a very high dropout rate, which is mentioned as the study's most prominent limitation. [26]. The authors tested the effects of additional therapist support on the program's effectiveness. The additional support did not contribute significantly to the study's outcomes [26]. This supports previous findings by Maercker et al [28] that web-based self-help interventions may be a promising treatment option for adjustment problems and further indicates that such interventions do not necessarily need scheduled guidance from a specialist.

Another unguided web-based program for adjustment problems is ZIEL [29]. The ZIEL program comprises different evidence-based techniques from treatments for depression, anxiety disorders and post-traumatic stress disorders. ZIEL consists of 5 sections which participants can work through freely and as needed over a course of 4 weeks. In an RCT, the participants of both the experimental and the control group showed an improvement in the severity of symptoms of adjustment problems. The intervention group, however, showed a significantly greater improvement in terms of depressive symptoms and quality of life. However, the authors of ZIEL also report challenges with high dropouts and suggest different measures to address this. One of these suggestions is to focus on certain subgroups of people with AjP, or on certain triggers of

AjP respectively. This, in turn, would allow for a more tailored response to the needs of the users, thereby creating a better user-program-fit and greater relevance for the users [29].

Rationale

Against the background that accidents can have various long-term psychological consequences such as AjP, which are often not or insufficiently treated, we have developed SelFIT. SelFIT is a German acronym standing for 'fit again after an accident' (German: Selber wieder fit nach einem Unfall). The program was realized as a web-based program in order to provide an easily accessible psychological treatment option to accident victims. Considering the results and conclusions from previous research on internet-based self-help interventions for AjP described above, SelFIT was not created as a treatment for AjP in general, but specifically for the treatment of psychological distress and AjP after an accident. This focus allows for a more specific thematic tailoring to the needs of the target population. Additionally, the guidance on demand approach was chosen in order to take advantage of as many benefits of guided and unguided programs as possible without generating excessive additional costs.

Aims and Objectives

The aim of this study is to conduct a randomized controlled trial to evaluate the new SelFIT program developed for people who experience AjP after an accident. Specifically, the objectives are

- to evaluate the efficacy and cost-effectiveness of SelFIT used in addition to CAU compared to only CAU.
- to analyze the acceptance and user-friendliness of the SelFIT program and draw conclusions for further developments of the program and the type of guidance applied in the program (i.e., guidance on demand).

- to explore and analyze moderators (eg, age, sex or satisfaction with the program), mediators (eg, adherence) and predictors (eg, adherence, embitterment or optimism) for the efficacy of the program.

Methods

Study Design

Overview

This study is a prospective longitudinal RCT. The study population are German-speaking adults (≥18 years) who suffer from adjustment problems after experiencing an accident within 2 weeks to 2 years before entering the study.

The lower time limit was set in order to reach injured persons as soon as possible after the accident and thereby prevent the development or worsening of psychological distress such as AjP. The upper time limit was set in accordance with the time criterion of a chronic adjustment disorder according to the current version of the International Classification of Diseases (ICD-10 [30]).

Figure 1 displays the study flowchart, illustrating that participants in the intervention group receive direct access while those in the control group receive access after 12 weeks. All participants are asked to complete the online assessment at 6 times. The first questionnaire (pre-measurement) serves both as a baseline and the screening for inclusion and exclusion criteria. There are two between-measurements after 4 and 8 weeks respectively. The post-measurement takes place after 12 weeks. All participants are asked to participate in the follow-up measurements taking place 24 and 36 weeks after randomization to evaluate the long-term effects of the intervention. Participants who dropped out at any point will be asked to participate in the following measurement(s) nonetheless.

Randomization

After the receipt of the informed consent and the initial screening, participants are randomized equally (1:1 ratio) into the treatment or the control group. Randomization is stratified by the point-value participants score on the questionnaire used as the primary outcome measure (12-16 points vs. ≥17 points) in order to make the two groups comparable regarding their symptom expression on this measure. This is done with a computerized random number generator and randomly permuted block sizes using Randomization.com [31]. Randomization within each stratum uses a 1:1 ration as well. The allocation schedule is generated by a researcher not involved in the research process and is unknown to the investigators.

Figure 1

Flowchart of the SelFIT study design
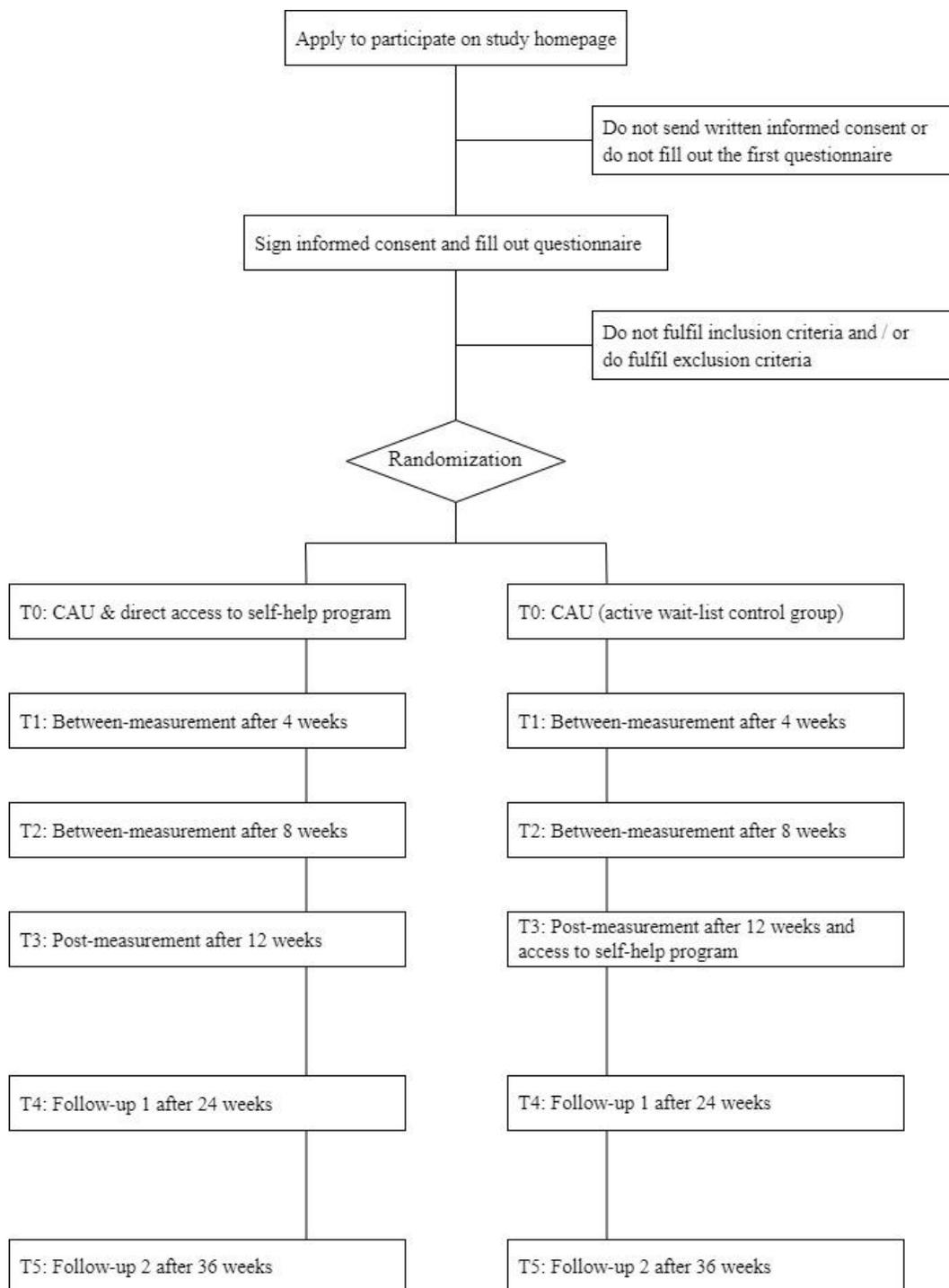
Recruitment

Overview

Recruitment takes place via advertising on social media, websites, internet forums, different organizations and self-help groups as well as through referrals from rehabilitation clinics, psychotherapeutic practices and clinics, physiotherapists, medical doctors and hospitals. People interested in participating can leave their contact details on the study home page and will then be sent the participant information according to their choice either by mail or by post. After the signed informed consent form is sent to the study team, potential participants are asked to complete the first online questionnaire to check if they do not meet any of the exclusion and meet all the inclusion criteria described below.

Eligibility Criteria

According to the inclusion criteria of this study, all participants must

- have experienced and be able to specify an accident during a period of 2 weeks to 2 years prior to participation in this study

- exceed the cut-off value for at least a mild psychological burden on the Depression Anxiety Stress Scale (DASS-21, [32])

- be at least 18 years old

- provide informed consent

- have access to the Internet

- master the German language

- be able to specify an emergency address in the event of an acute crisis

Excluded are persons who

- show severe depressive symptoms (Beck Depression Inventory [BDI-II, 33] > 29)

- show suicidal tendencies (BDI-II suicide item > 1)

- have a known diagnosis of a psychotic or bipolar disorder

Description of the Intervention

The SelFIT program takes 12 weeks in total. It consists of an introduction, 8 thematic modules, and a conclusion. The thematic modules are described in Textbox 1. Furthermore, the program comprises a page with information about the procedure to be followed in emergencies and acute crises as well as a list of suitable contacts in such situations. Multimedia Appendix 1 shows a screenshot of the program's homepage.

Participants are encouraged to work on one module per week and to repeat and deepen the various exercises during the last 4 weeks of the program in order to facilitate the transfer to their own everyday life. However, participants are free to choose both the order and speed of processing of the modules themselves. All modules consist of a video, various texts, exercises and weekly tasks. In addition, participants are asked to indicate, which of a list of feelings, moods and physical conditions the currently experience. This allows them to observe how their well-being changes over the course of the program.

Since the study employs a guidance on demand approach, participants can contact the study team if needed or desired. For this purpose, they can either write an e-mail or use the chat function within the program. In the settings, there is also the option to choose whether participants want to receive a reminder e-mail after a certain period of inactivity. Other than this, contact with the study team, a therapist or counsellor is not planned by default.

Textbox 1

Outline of the thematic modules of the SelFIT program

Module 1: Accidents and their consequences
- Information about psychological and physical consequences of accidents as well as the symptoms of adjustment problems
- Survey of the participant's current situation and well-being

Module 2: Changing perspectives
- Information on automatic and irrational assumptions, chains of thoughts and the influence of thoughts and assumptions on one's state of mind
- Exercises with the aim of cognitive restructuring

Module 3: Understanding different reactions to accidents
- Information about frequent psychological reactions to accidents
- Exercise to identify physical symptoms of anxiety

Module 4: Activation
- Behavioral activation with suggestions for different types of activation
- Development of a personal activity plan
- Information about the importance of physical activity

Module 5: Self-care
- Information about post-traumatic growth
- Exercises to promote acceptance, gratitude for positive aspects of life and personal resources

Module 6: Finding calm
- Information about sleep and sleep hygiene
- Exercises to promote mental and physical relaxation

Module 7: Addressing painful feelings
- Information about typical reasoning errors
- Information about and exercises for dealing with painful feelings such as guilt, shame, anger and resentment after an accident

Module 8: Self-efficacy
- Information about attribution styles, self-fulfilling prophecies and self-instructions
- Identification and activation of personal resources
- Exercise to promote self-confidence

Measures

All instruments used over the course of the study are self-report questionnaires that are completed online. Figure 2 gives an overview of all questionnaires with the time points of the assessments. Since the study population is German speaking, we use the German version for all questionnaires.

Primary Outcome Measure

The primary outcome measure is the short version of the Depression Anxiety Stress Scale with 21 items [32]. Each of this questionnaire's three scales contains 7 items assessing symptoms of depression, anxiety and stress on a 4-point Likert-scale ranging from 0=never to 3=almost always. The DASS-21 is not diagnosis-specific and has proven to be a well-suited measure of psychological distress in a broad range of clinical and non-clinical samples [34, 35]. This is why we use this questionnaire to assess symptoms of psychological distress and AjP.

Further Outcome Measures

Adjustment Problems and Depressive Symptoms. AjP are also assessed using the Adjustment Disorder – New Module 20 [36]. The questionnaire was designed according to the upcoming ICD-11 symptom definition of adjustment disorder. It consists of 20 items, which are divided into a stressor list and an item list. While the stressor list captures different acute and chronic life events, the item list assesses the symptoms occurring in response to those stressors. In accordance with the ICD-11 definition of adjustment disorder these symptoms are based on the adjustment disorder core symptoms of avoidance, anxiety, impulse disturbance and depressive mood [36].

Depressive symptoms are additionally assessed using the Beck Depression Inventory II [33]. This questionnaire consists of 21 items which are rated on a Likert-scale ranging from

0=not at all to 3=very strong. Item 9 of this instrument is also used to screen for suicidality at all 6 measurement points of the study.

Accident-related Measures. Regarding the accident, we ask for a short description of the event, the time that has passed since as well as its subjectively perceived severity.

Pain due to the accident is assessed by the Brief Pain Inventory [37], which consists of 15 items. After the question of whether there is any pain that exceeds the normal levels expected in everyday life, participants have to indicate where the pain is located and how severe the limitations in various areas of life are due to the pain. We also assess the participants' own perception of their physical attractiveness. Physical attractiveness is a very influential informational cue that is used frequently and consistently [38, 39]. It has been shown to play an important role in how a person is perceived and responded to in many areas of life [38]. This includes health and psychological well-being. Bordieri et al [40] found that physical attractiveness influenced how others make attributions concerning the cause and prognosis of someone's disability. Physical attractiveness was also linked to self-esteem [40]. Among the possible consequences of an accident is skin scarring. In most cases, this is perceived as unattractive [41]. Brown et al [41] found that skin scars impact a person's acceptability to others as well as themselves and also have an effect on social functioning and emotional well-being. Thus, participants in this study are asked to rate their own physical attractiveness compared to that of other people their age. They also have to indicate how often they think about being rated by others in terms of physical attractiveness. Furthermore, it is assessed if and how much the participants' own perception of their physical attractiveness has changed since the accident.

Cost-effectiveness Measures. Two questionnaires with a different emphasis are used to assess the cost-effectiveness of the SelFIT program. The costs of health care consumption and

productivity loss are assessed using the Treatment inventory of Costs in Psychiatric Patients [42], a self-report questionnaire with 23 items of varying answer formats. Work-related factors with regard to the consequences of the accident are assessed by means of the Work and Health Questionnaire [43]. This questionnaire consists of 3 different parts with a total of 21 items with varying answer formats. The first part contains 5 items on current work activity, the second part contains 7 items on workload and cooperation, and the third part contains 9 items on health and well-being.

Embitterment and Optimism. We also assess embitterment and optimism. For this we use the Bern Embitterment Inventory [44], an 18-item questionnaire with answers ranging from 0=not at all true to 4=exactly true, is used to survey embitterment. Optimism is assessed by the Life Orientation Test Revised [45], which consists of 10 items with answer categories ranging from 0=strongly disagree to 4=strongly agree.

General well-being and the ability to cope in everyday life are assessed by the Short Form 12 Health Survey [46]. The questionnaire consists of 12 items with different answer designs and -options.

Self-esteem, Self-efficacy and Emotion Regulation Skills. Furthermore, we assess self-esteem, self-efficacy and emotion regulation skills. Self-esteem is measured using the Rosenberg Self-esteem Scale [47]. This scale consists of 10 items with a 4-point scale from 0=strongly agree to 3=strongly disagree.

The General Self-Efficacy Scale [48] serves as a measure to assess perceived self-efficacy aiming to predict coping with daily hassles and general adjustment after experiencing a stressful life event. The scale comprises 10 items on a scale from 1=not at all true to 4=exactly true. Emotion regulation skills are assessed via the Self-Report Measure for the Assessment of

Emotion Regulation Skills [49], a 27-item questionnaire with answers ranging from 0=not at all

to 3= (almost) always.

Program-related Measures. The program-related factors we survey include user

satisfaction and program usability. This is assessed using the Client Satisfaction Questionnaire

[50, 51], an 8-item scale with a 4-tiered answer format varying in its wording. The program's

usability is measured with the System Usability Scale [52], which consists of 10 items with

answers ranging from 1=do not agree at all to 5=completely agree.

A further program-related factor is adherence measured by the frequency and duration of

use. Those parameters are gathered within the program, for example by means of the number of

logins or the percentage of pages and segments that have been accessed and browsed through at

least once.

Demographic Variables. Demographic variables obtained from the first online

questionnaire include gender, age, family status as well as level of income and education.

Additionally, participants are asked to indicate whether they have received or currently receive

any treatment for mental health issues and or physical rehabilitation.

Data Collection and Management

All data is assessed online, either within the program platform or via online-

questionnaires programmed in Qualtrics [53]. Data integrity is enforced through different

mechanisms including referential data rules, valid values, range checks and consistency checks.

The option to choose a value from a list of valid codes and a description of what each code

means will be available where applicable. Checks are applied at the time of data entry into a

specific field. All data is stored in anonymous form and can only be traced by a code that cannot

be linked to the identity of the participant. Data gathered within the program as well as the

program itself are stored on a firewall-encrypted back-upped server of the University of Bern.

Only researchers directly involved in the study have access to the data and are subject to

professional discretion.

Figure 2

SPIRIT figure to display the study's schedule of enrolment, interventions, and assessments

	STUDY PERIOD						
	Enrolment	Allocation	Post-allocation				
TIMEPOINT	t_0	**0**	*t1: BTM-1*	*t2: BTM-2*	*t3: Post*	*t4: Follow-up 1*	*T5: Follow-up 2*
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
SelFIT direct access + CAU			◆――――――――◆				
Waitlist control group + CAU						◆――◆	
ASSESSMENTS:							
Baseline • Depression Anxiety Stress Scale • Adjustment Disorder New Module 20 • Beck Depression Inventory II • Brief Pain Inventory • Treatment inventory of Costs in Psychiatric Patients • Work and Health Questionnaire • Short Form Health Survey • Bern Embitterment Inventory • Life Orientation Test Revised • Rosenberg Self-esteem Scale • General Self-Efficacy Scale • Emotion Regulation Skills • Demographic variables	X						
Primary Outcome Measure • Depression Anxiety Stress Scale			X	X	X	X	X
Further Outcome Measures • Beck Depression Inventory II			X	X	X	X	X
• Adjustment Disorder – New Module 20 • Brief Pain Inventory • Work and Health Questionnaire • Short Form Health Survey • Bern Embitterment Inventory • Rosenberg Self-esteem Scale • General Self-Efficacy Scale Emotion Regulation Skills					X	X	X
• Treatment inventory of Costs in Psychiatric Patients							X
• Client Satisfaction Questionnaire • System Usability Scale • Duration and intensity of use					X	X	

Power

In order to specify the sample size needed for the planned analyses we conducted a power analysis based on a probability level of 0.05 and a power of 0.80 using G*Power[54]. To test the program's efficacy compared to the control group we expect small-to-moderate effect sizes between d=0.2 and d=0.35 as well as a correlation between the groups of r=0.4. Those estimates are based on the results of previous web-based interventions for adjustment problems (eg, [29]).

The a-priori power analyses yielded a necessary sample size of 80 (for d=0.35) to 238 (for d=0.2) participants in total for this analysis. Since the program does not include weekly guidance but guidance on demand, we expect slightly smaller effect sizes. Based on these calculations and assumptions we decided to target a sample size of N=240 participants.

Statistical Analysis

Statistical analyses will be carried out on the basis of the intention-to-treat (ITT) approach and therefore will include all randomized participants. We will analyze the extent of the missing data, explore patterns and determine the type of missing data (Missing Completely at Random, Missing at Random, Not Missing at Random). Missing values will be substituted using multiple imputations. Sensitivity analyses will be conducted for both the datasets with and without the imputed data.

We will use linear mixed models to analyze all continuous outcomes as a change from baseline to compare effects between the two groups and over the different measurement points. In case of a missing at random mechanism, we will conduct multilevel regression analyses, which are less sensitive to missing data. Multiple regression analyses allow us to include several predictors such as time of measurement or group allocation [55].

Furthermore, exploratory analyses will be conducted. One of these will examine the association between adherence and outcome, since a higher adherence has been shown to have a positive effect on outcome (eg, [56, 57]). All analyses will be conducted using SPSS and R.

Results

The study is conducted according to the principles of the World Medical Assembly Declaration of Helsinki [58], the Swiss Federal Human Research Act (German: HFG) [59] as well as the Ordinance on Clinical Trials in Human Research (German: KlinV) [60]. Ethical approval has been obtained by the Cantonal Ethics Committee Berne (BASEC 2018-01059). The study is registered with ClinicalTrials.gov (NCT03785912). Furthermore, the SelFIT program is a CE-certified medical device. Written informed consent is obtained from each participant.

Recruitment, screening, inclusion and randomization of participants is scheduled to take place between December 2019 and January 2021. Due to the COVID-19 pandemic, recruitment was slowed down. For this reason, the recruitment phase may be extended by 6 months if we are unable to recruit enough participants by the end of January 2021.

As of July 2020, 324 people have shown interest in participating and 48 people have given their informed consent. We are confident to be able to recruit enough people for three reasons. Firstly, a recruitment cooperation with one of the largest rehabilitation clinics for injured persons in Switzerland will start in August. This means a steady influx of participants. Secondly, all persons who have expressed interest in participating but have not registered are contacted again and asked if they would like to participate in the study. This has proven to be an effective strategy so far. Thirdly, we can extend the recruitment phase if necessary. The project's recruitment schedule is shown in Figure 3.

Figure 3

Gantt Chart displaying the study's recruitment schedule and status of recruitment
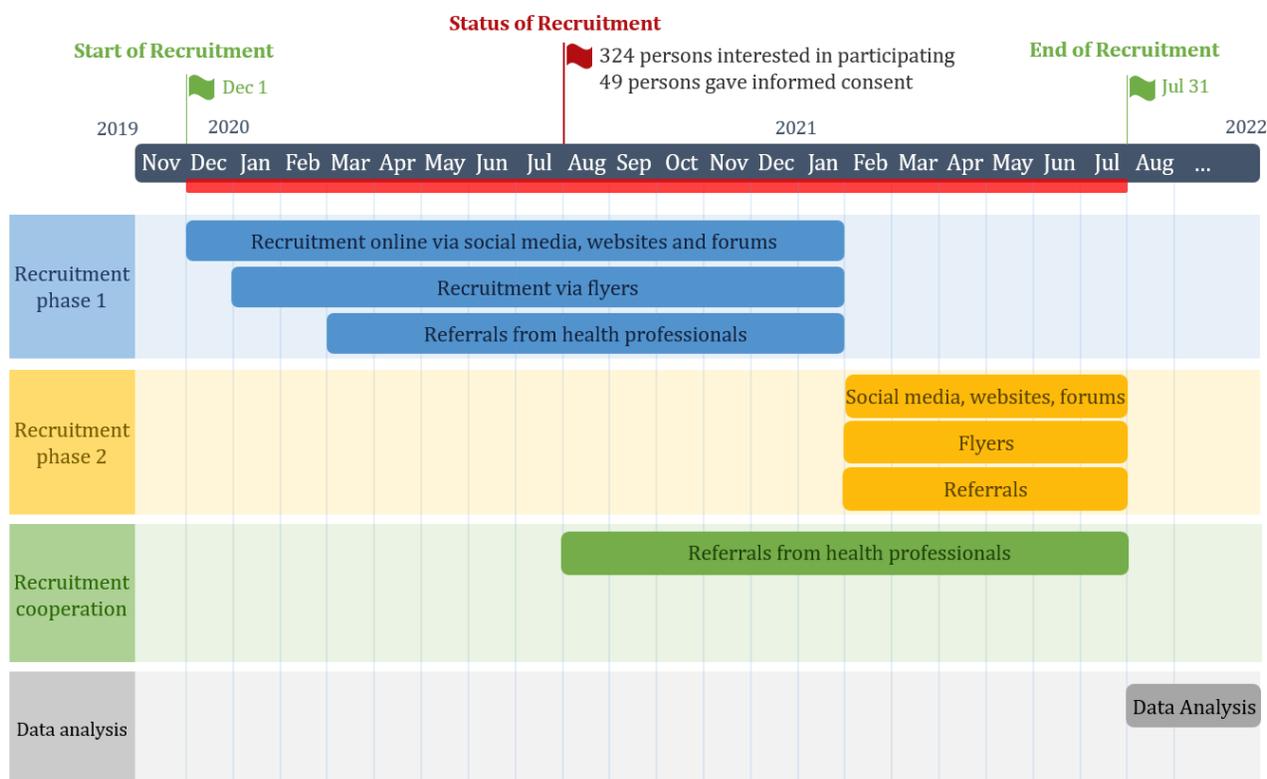
Discussion

Principal Findings

Accidents and their consequences often affect not only a person's physical well-being but also their mental health and their professional, personal and social environment. Thus, accidents often mean a significant change and new challenges for those affected. Adjusting to those changed circumstances can be difficult. This also applies to adjustment efforts when returning to everyday life after rehabilitation is over, for example. A lack of support during this time may lead to the development or worsening of psychological distress such as adjustment problems. Easily accessible treatment options such as the SelFIT program could remedy this situation. For

this reason, SelFIT was implemented as a web-based self-help intervention, which allows a high degree of flexibility in terms of time and location and can be used with comparatively little effort. Based on the findings of previous studies on AjP and internet-based interventions, SelFIT comprises a guidance on demand approach. This enables users to obtain support when needed with minimal personnel costs. Unlike previous web-based programs on AjP, SelFIT does not address AjP in general. Instead, the focus is specifically on the treatment of psychological distress and AjP after an accident. This allows the content of the program to be matched more specifically to the needs of the participants.

To the best of our knowledge, this combination of web-based delivery, guidance on demand and the focus on the psychological support of injured persons has not yet been done yet.

Due to this novel approach, SelFIT could also contribute to expanding the scope of therapy options and offers of clinics, practices or hospitals. Here, the program could serve as a supplement to face-to-face therapy. In addition, SelFIT can also offer extended psychological support, for example after the end of a rehabilitation program in the transition to everyday life at home or as a transitional offer after the end of psychotherapy.

The results of this study will provide insight into the efficacy and cost-effectiveness of the SelFIT program. The analysis of the program's user-friendliness and adherence may provide information for further adaptations to different user needs.

Limitations

Possible limitations of this study include typical challenges of web-based interventions such as the self-selection of participants. This is addressed by recruiting through various channels, such as program referrals from a rehabilitation clinic for injured people, recruitment via social media or recommendations by physiotherapists. Another potential limitation are

participants' physical restrictions due to the accident, which make it difficult to use a computer or other technical devices. In such a case, access to the program might be limited.

The narrow focus of participants to be included in the study can have disadvantages. Although this allows for more specific tailoring, it makes the target population significantly smaller and recruitment more difficult.

Author's Contributions

Initially, this study was conceptualized by TB and HZ. JH developed the intervention and the design of the study, recruited the participants and drafted the manuscript. NB developed the intervention and the design of the study, and recruited the participants. The manuscript was reviewed and edited prior to submission and all authors approved the final version.

Conflicts of Interest

None declared.

Multimedia Appendix

Screenshot of the SelFIT program's homepage

References

1. Arienti C, Gimigliano F, Pollet J, Kiekens C, Negrini S. [Cochrane and World Health Organization "Rehabilitation 2030: a call for action".]. Recenti progressi in medicina. 2018 Feb;109(2):149-50. PMID: 29493645. doi: 10.1701/2865.28914.

2. Gimigliano F, Negrini S. The World Health Organization "Rehabilitation 2030: a call for action". European journal of physical and rehabilitation medicine. 2017 Apr;53(2):155-68. PMID: 28488425 doi: 10.23736/s1973-9087.17.04746-3.

3. Angenendt J. Psychische Folgen von Unfällen und deren Versorgung. Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz. 2014 June 01;57(6):666-72. PMID: 24863709. doi: 10.1007/s00103-014-1967-7.

4. Angenendt J, Nyberg E, Frommberger U. Posttraumatische Belastungsreaktionen bei Verkehrsunfallopfern. In: Maercker A, editor. Posttraumatische Belastungsstörungen. Berlin, Heidelberg: Springer Berlin Heidelberg; 2009. p. 501-15.

5. Angenendt J, Drechsel-Schlund C, Südkamp N, Berger M. Notfallmedizin und Unfallchirurgie: Psychotraumatologie nach Unfällen. Dtsch Arztebl International. 2016 October 7, 2016;113(40):1752-4.

6. Kühn M. *Die psychischen Folgen von schweren Unfällen und ihre Prädiktoren*. Zürich: Philosophische Fakultät, Universität Zürich; 2005. DOI: https://doi.org/10.5167/uzh-165153

7. Giummarra MJ, Lennox A, Dali G, Costa B, Gabbe BJ. Early psychological interventions for posttraumatic stress, depression and anxiety after traumatic injury: A systematic review and meta-analysis. Clinical psychology review. 2018 Jun;62:11-36. PMID: 29754102. doi: 10.1016/j.cpr.2018.05.001.

8. Shih RA, Schell TL, Hambarsoomian K, Belzberg H, Marshall GN. Prevalence of
    Posttraumatic Stress Disorder and Major Depression After Trauma Center Hospitalization.
    Journal of Trauma and Acute Care Surgery. 2010;69(6):1560-6. PMID: 20693915. doi:
    10.1097/TA.0b013e3181e59c05.

9. Bryant RA, Nickerson A, Creamer M, O'Donnell M, Forbes D, Galatzer-Levy I, et al.
    Trajectory of post-traumatic stress following traumatic injury: 6-year follow-up. British
    Journal of Psychiatry. 2015;206(5):417-23. PMID: 25657356 doi:
    10.1192/bjp.bp.114.145516.

10. Ben-Ezra M, Mahat-Shamir M, Lorenz L, Lavenda O, Maercker A. Screening of adjustment
    disorder: Scale based on the ICD-11 and the Adjustment Disorder New Module. Journal of
    Psychiatric Research. 2018 2018/08/01/;103:91-6. PMID: 29803077. doi:
    https://doi.org/10.1016/j.jpsychires.2018.05.011.

11. O'Donnell ML, Alkemade N, Creamer M, McFarlane AC, Silove D, Bryant RA, et al. A
    Longitudinal Study of Adjustment Disorder After Trauma Exposure. The American journal
    of psychiatry. 2016 Dec 1;173(12):1231-8. PMID: 27771970. doi:
    10.1176/appi.ajp.2016.16010071.

12. Casey P, Jabbar F, O'Leary E, Doherty AM. Suicidal behaviours in adjustment disorder and
    depressive episode. Journal of affective disorders. 2015 2015/03/15/;174:441-6. PMID:
    25553405. doi: https://doi.org/10.1016/j.jad.2014.12.003.

13. Forneris CA, Gartlehner G, Brownley KA, Gaynes BN, Sonis J, Coker-Schwimmer E, et al.
    Interventions to Prevent Post-Traumatic Stress Disorder: A Systematic Review. American
    Journal of Preventive Medicine. 2013 2013/06/01/;44(6):635-50. PMID: 23683982. doi:
    https://doi.org/10.1016/j.amepre.2013.02.013.

14. Andersson G, Titov N. Advantages and limitations of internet-based interventions for common mental disorders. World Psychiatry. 2014;13. PMID: 24497236. doi: 10.1002/wps.20083.

15. Cuijpers P, Donker T, Johansson R, Mohr DC, van Straten A, Andersson G. Self-guided psychological treatment for depressive symptoms: a meta-analysis. PLoS One. 2011;6(6):e21274. PMID: PMC3119687. doi: 10.1371/journal.pone.0021274.

16. Baumeister H, Reichler L, Munzinger M, Lin J. The impact of guidance on Internet-based mental health interventions — A systematic review. Internet Interventions. 2014 2014/10/01/;1(4):205-15. 2214-7829https://doi.org/10.1016/j.invent.2014.08.003. doi: https://doi.org/10.1016/j.invent.2014.08.003.

17. Andersson G, Cuijpers P. Internet-based and other computerized psychological treatments for adult depression: a meta-analysis. Cognitive behaviour therapy. 2009;38(4):196-205. PMID: 20183695. doi: 10.1080/16506070903318960.

18. Mohr DC, Duffecy J, Ho J, Kwasny M, Cai X, Burns MN, et al. A randomized controlled trial evaluating a manualized TeleCoaching protocol for improving adherence to a web-based intervention for the treatment of depression. PloS one. 2013;8(8):e70086-e. PMID: 23990896. doi: 10.1371/journal.pone.0070086.

19. Donkin L, Christensen H, Naismith SL, Neal B, Hickie IB, Glozier N. A Systematic Review of the Impact of Adherence on the Effectiveness of e-Therapies. Journal of medical Internet research. 2011;13(3):e52. PMID: 21821503. doi: 10.2196/jmir.1772.

20. Kleiboer A, Donker T, Seekles W, Straten A, Riper H, Cuijpers P. A randomized controlled trial on the role of support in Internet-based problem solving therapy for depression and

anxiety. Behaviour research and therapy. 2015 07/06;72:63-71. PMID: 26188373. doi: 10.1016/j.brat.2015.06.013.

21. Rheker J, Andersson G, Weise C. The role of "on demand" therapist guidance vs. no support in the treatment of tinnitus via the internet: A randomized controlled trial. Internet Interventions. 2015 2015/05/01;2(2):189-99. 2214-7829https://doi.org/10.1016/j.invent.2015.03.007. doi: https://doi.org/10.1016/j.invent.2015.03.007.

22. Krieger T, Reber F, von Glutz B, Urech A, Moser CT, Schulz A, et al. An Internet-Based Compassion-Focused Intervention for Increased Self-Criticism: A Randomized Controlled Trial. Behavior Therapy. 2019 2019/03/01;50(2):430-45. PMID: 30824257. doi: https://doi.org/10.1016/j.beth.2018.08.003.

23. Rachyla I, Pérez-Ara M, Molés M, Campos D, Mira A, Botella C, et al. An internet-based intervention for adjustment disorder (TAO): study protocol for a randomized controlled trial. BMC Psychiatry. 2018 May 31;18(1):161. 1471-244X10.1186/s12888-018-1751-6. doi: 10.1186/s12888-018-1751-6.

24. Rachyla I, Quero S, Pérez-Ara M, Molés M, Campos D, Mira A. Web-based, self-help intervention for adjustment disorders: acceptance and usability. Annu Rev Cybertherapy Telemed. 2017;15.

25. Skruibis P, Eimontas J, Dovydaitiene M, Mazulyte E, Zelviene P, Kazlauskas E. Internet-based modular program BADI for adjustment disorder: protocol of a randomized controlled trial. BMC Psychiatry. 2016 Jul 26;16:264. PMID: PMC4960748. doi: 10.1186/s12888-016-0980-9.

26. Eimontas J, Rimsaite Z, Gegieckaite G, Zelviene P, Kazlauskas E. Internet-Based Self-Help Intervention for ICD-11 Adjustment Disorder: Preliminary Findings. Psychiatr Q. 2018 Jun;89(2):451-60. 0033-272010.1007/s11126-017-9547-2. doi: 10.1007/s11126-017-9547-2.

27. Skruibis P, Eimontas J, Dovydaitiene M, Mazulyte E, Zelviene P, Kazlauskas E. Internet-based modular program BADI for adjustment disorder: protocol of a randomized controlled trial. BMC Psychiatry. 2016 July 26;16(1):264. 1471-244X10.1186/s12888-016-0980-9. doi: 10.1186/s12888-016-0980-9.

28. Maercker A, Bachem RC, Lorenz L, Moser CT, Berger T. Adjustment disorders are uniquely suited for ehealth interventions: concept and case study. JMIR Ment Heal. 2015;2. 10.2196/mental.4157. doi: 10.2196/mental.4157.

29. Moser C, Bachem R, Berger T, Maercker A. ZIEL: Internet-Based Self-Help for Adjustment Problems: Results of a Randomized Controlled Trial. Journal of Clinical Medicine. 2019 10/11;8:1239. PMID: 31614528. doi: 10.3390/jcm8101655.

30. Organization WH. The ICD-10 Classification of Mental and Behavioural Disorders: clinical descriptions and diagnostic guidelines. Geneva: World Health Organization; 1992. ISBN: 9241544228.

31. Dallal GE. Randomization.com. 2008 [updated 07/16/2008; cited 2020 02/07/2020]; Available from: http://www.randomization.com.

32. Lovibond SH, Lovibond PF. Manual for the Depression Anxiety Stress Scales. Sydney: Psychology Founation of Australia; 1995. ISBN: 7334-1423-0.

33. Beck AT, Steer RA, Brown GK. Manual for the Beck depression inventory-II. San Antonio, TX: Psychological Corporation; 1996.

34. Osman A, Wong JL, Bagge CL, Freedenthal S, Gutierrez PM, Lozano G. The Depression Anxiety Stress Scales—21 (DASS-21): Further Examination of Dimensions, Scale Reliability, and Correlates. Journal of Clinical Psychology. 2012;68(12):1322-38. PMID: 22930477. doi: 10.1002/jclp.21908.

35. Szabó M. The short version of the Depression Anxiety Stress Scales (DASS-21): Factor structure in a young adolescent sample. Journal of Adolescence. 2010 2010/02/01/;33(1):1-8. PMID: 19560196. doi: https://doi.org/10.1016/j.adolescence.2009.05.014.

36. Lorenz L, Bachem RC, Maercker A. The Adjustment Disorder - New Module 20 as a Screening Instrument: Cluster Analysis and Cut-off Values. The international journal of occupational and environmental medicine. 2016 Oct;7(4):215-20. PMID: 27651082. doi: 10.15171/ijoem.2016.775.

37. Cleeland C, Ryan K. Pain assessment: global use of the Brief Pain Inventory. Annals, Academy of Medicine, Singapore. 1994. PMID: 8080219.

38. Patzer GL. The physical attractiveness phenomena: Springer Science & Business Media; 2012. ISBN: 1475702027.

39. Patzer GL. Self-esteem and physical attractiveness. Journal of Esthetic and Restorative Dentistry. 1995;7(6):274-6. PMID: 8615992. doi: 10.1111/j.1708-8240.1995.tb00591.x.

40. Bordieri JE, Sotolongo M, Wilson M. Physical attractiveness and attributions for disability. Rehabilitation Psychology. 1983;28(4):207. 1939-1544 https://doi.org/10.1037/h0090976. doi: https://doi.org/10.1037/h0090976.

41. Brown BC, McKenna SP, Siddhi K, McGrouther DA, Bayat A. The Hidden Cost of Skin Scars: Quality of Life After Skin Scarring. J Plast Reconstr Aesthet Surg. 2008

2008/09/01/;61(9):1049-58. PMID: 18617450. doi:

https://doi.org/10.1016/j.bjps.2008.03.020.

42. Bouwmans C, De Jong K, Timman R, Zijlstra-Vlasveld M, Van der Feltz-Cornelis C, Tan

Swan S, et al. Feasibility, reliability and validity of a questionnaire on healthcare

consumption and productivity loss in patients with a psychiatric disorder (TiC-P). BMC

health services research. 2013 Jun 15;13:217. PMID: PMC3694473. doi: 10.1186/1472-

6963-13-217.

43. Abegglen S, Hoffmann-Richter U, Schade V, Znoj HJ. Work and Health Questionnaire

(WHQ): A Screening Tool for Identifying Injured Workers at Risk for a Complicated

Rehabilitation. Journal of occupational rehabilitation. 2017 Jun;27(2):268-83. PMID:

27393558. doi: 10.1007/s10926-016-9654-1.

44. Znoj HJ. Berner Verbitterungs-Inventar. Bern: Verlag Hans Huber; 2008.

45. Herzberg PY, Glaesmer H, Hoyer J. Separating optimism and pessimism: a robust

psychometric analysis of the revised Life Orientation Test (LOT-R). Psychological

assessment. 2006 Dec;18(4):433-8. PMID: 17154764. doi: 10.1037/1040-3590.18.4.433.

46. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of

scales and preliminary tests of reliability and validity. Medical care. 1996 Mar;34(3):220-33.

PMID: 8628042.

47. von Collani G, Herzberg PY. Eine revidierte Fassung der deutschsprachigen Skala zum

Selbstwertgefühl von Rosenberg. Zeitschrift für differentielle und diagnostische

Psychologie. 2003;24(1):3-7. https://doi.org/10.1024//0170-1789.24.1.3. doi:

https://doi.org/10.1024//0170-1789.24.1.3.

48. Jerusalem M, Schwarzer R. Skala zur allgemeinen Selbstwirksamkeitserwartung. Dokumentation der psychometrischen Verfahren im Rahmen der Wissenschaftlichen Begleitung des Modellversuchs Selbstwirksame Schulen. Berlin: Freie Universität Berlin; 1999. ISBN: 3-00-003708-X.

49. Berking M, Znoj HJ. Entwicklung und Validierung eines Fragebogens zur standardisierten Selbsteinschätzung emotionaler Kompetenzen (SEK-27). Zeitschrift für Psychiatrie, Psychologie und Psychotherapie. 2008;56(2):141-53. 10.1024/1661-4747.56.2.141. doi: 10.1024/1661-4747.56.2.141.

50. Attkisson CC, Zwick R. The client satisfaction questionnaire. Psychometric properties and correlations with service utilization and psychotherapy outcome. Evaluation and program planning. 1982;5(3):233-7. PMID: 10259963.

51. Schmidt J, Lamprecht F, Wittmann WW. Zufriedenheit mit der stationären Versorgung. Entwicklung eines Fragebogens und erste Validitätsuntersuchungen. Psychotherapie Psychosomatik Medizinische Psychologie. 1989;39:248-55. PMID: 2762479.

52. Brooke J. System Usability Scale (SUS): A Quick-and-Dirty Method of System Evaluation User Information. In: Jordan PW, Thomas B, McClelland IL, Weerdmeester B, editors. Usability Evaluation in Industry. Philadelphia: Taylor and Francis; 1996.

53. Qualtrics. Qualtrics. May 2020 ed. Provo, Utah, USA: Qualtrics; 2020.

54. Faul F, Erdfelder E, Buchner A, Lang A-GG. Power 3 : a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods. 2007;39. 10.3758/bf03193146. doi: 10.3758/bf03193146.

55. Brodbeck J, Berger T, Znoj HJ. An internet-based self-help intervention for older adults after marital bereavement, separation or divorce: study protocol for a randomized controlled trial. Trials. 2017 Jan 13;18(1):21. PMID: PMC5237350. doi: 10.1186/s13063-016-1759-5.

56. Fuhr K, Schröder J, Berger T, Moritz S, Meyer B, Lutz W, et al. The association between adherence and outcome in an Internet intervention for depression. Journal of affective disorders. 2018 Mar 15;229:443-9. PMID: 29331706. doi: 10.1016/j.jad.2017.12.028.

57. Simpson HB, Maher MJ, Wang Y, Bao Y, Foa EB, Franklin M. Patient adherence predicts outcome from cognitive behavioral therapy in obsessive-compulsive disorder. Journal of consulting and clinical psychology. 2011;79(2):247-52. PMID: 21355639. doi: 10.1037/a0022659.

58. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. Jama. 2013 Nov 27;310(20):2191-4. PMID: 24141714 doi: 10.1001/jama.2013.281053.

59. Bundesgesetz über die Forschung am Menschen, SR 810.30 (2014). https://www.admin.ch/opc/de/official-compilation/2013/3215.pdf. Accessed May 18 2020

60. Verordnung über klinische Versuche in der Humanforschung, SR 810.305 KlinV(2014). https://www.admin.ch/opc/de/official-compilation/2013/3407.pdf. Accessed May 15 2020

Abbreviations

AjP: Adjustment problems

CAU: Care as usual

ICD: International Classification of Diseases

RCT: Randomized controlled trial

WHO: World Health Organization

2.4 Article 4: An internet-based self-help intervention for people with psychological distress due to COVID-19: study protocol for a randomized controlled trial

Brog, N. A., Hegy, J. K., Berger, T., & Znoj, H. (2021). An internet-based self-help intervention for people with psychological distress due to COVID-19: study protocol for a randomized controlled trial. *Trials, 22*(1), 1–11. https://doi.org/10.1186/s13063-021-05089-9

An internet-based self-help intervention for people with psychological distress due to COVID-19: study protocol for a randomized controlled trial

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Abstract

Background: The Coronavirus-19 (COVID-19) has reached pandemic status and is affecting countries all over the world. The COVID-19 pandemic is accompanied by various stressors that require adjustment in everyday life and possibly changes in personal future prospects. While some individuals cope well with these challenges, some develop psychological distress including depressive symptoms, anxiety or stress. Internet-based self-help interventions have proven to be effective in the treatment of various mental disorders such as depression and anxiety. Based on that, we developed an internet-based self-help program for individuals with psychological distress due to the situation surrounding the COVID-19 pandemic. The 3-week self-help program consists of 6 modules comprising texts, videos, figures and exercises. Participants can request guidance within the self-help program (guidance on demand). The primary aim of this study is to evaluate the efficacy and feasibility of the self-help program compared to a waiting control condition.

Methods: The design is a parallel group randomized controlled trial. Participants are allocated to a 3-week self-help intervention plus care as usual or a 3-week waiting period with only care as usual. There are follow-ups after 6 weeks and 18 weeks. At least 80 participants with COVID-19 pandemic related psychological distress will be recruited. Primary outcome are depressive symptoms. Secondary outcomes include anxiety and chronic stress, suicidal experiences and behaviour, health-related quality of life, generalized optimism and pessimism, embitterment, optimistic self-beliefs, emotion regulation skills, loneliness, resilience and the satisfaction with and usability of the self-help program.

Discussion: To the best of our knowledge, this is one of the first studies investigating the efficacy of an internet-based self-help program for psychological distress due to the situation

surrounding the COVID-19 pandemic. Thus, the results of this study may give further insight into the use of internet-based self-help programs in pandemic-related psychological distress.

Trial registration: ClinicalTrials.gov, NCT04380909, Retrospectively registered on 8 May 2020, https://clinicaltrials.gov/ct2/show/NCT04380909

Keywords: Anxiety, Coronavirus, COVID-19, Depression, Internet-based self-help, Psychological distress, Randomized controlled trial, Stress

Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The

order of the items has been modified to group similar items (see http://www.equator-

network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-

clinical-trials/).

Title {1}	An internet-based self-help intervention for people with psychological distress due to COVID-19: study protocol for a randomized controlled trial.
Trial registration {2a and 2b}	ClinicalTrials.gov, NCT04380909, Retrospectively registered on 8 May 2020
Protocol version {3}	2021 January 28, Version 3
Funding {4}	The study is entirely funded by the University of Bern.
Author details {5a}	NB[1], JH[1], TB[1], and HZ[1] [1]Department of Psychology, University of Bern
Name and contact information for the trial sponsor {5b}	Trial Sponsor: University of Bern Contact name: Prof. Dr. HZ Address: Fabrikstrasse 8, 3012 Bern, Switzerland Telephone: +41 31 631 45 91 Email: hansjoerg.znoj@psy.unibe.ch
Role of sponsor {5c}	The funding body (University of Bern) played no role in the design of the study, the collection, analysis and interpretation of data or in writing the manuscript. However, the trial sponsor is the principal investigator of the study (sponsor investigator).

Introduction

Background and rationale {6a}

The Coronavirus-19 (COVID-19) has reached pandemic status and is affecting countries all over the world. Health systems are facing major challenges: In addition to the risks for physical health, the COVID-19 pandemic also represents a burden for mental health [1]. Pandemic related stressors such as quarantine, social isolation/distancing, unemployment, financial losses, caregiver stress and confrontation with illness and death can have a negative impact on mental health [1]. For example, in a study on the severe acute respiratory syndrome (SARS) pandemic, approximately 40% of the study population experienced increased stress related to work, finances and family and 16% showed signs of posttraumatic stress [2]. Preliminary research on the psychological impact of the COVID-19 pandemic indicates increased levels of psychological distress in the general population [3, 4]. Symptoms of anxiety, depression and self-reported stress, are suggested psychological reactions to the COVID-19 pandemic [5, 6].

Although pandemics comprise a multitude of stressors that may strain mental health, not everybody is experiencing psychological distress in response. Moreover, individuals might differ in the amount and kind of stressors they are exposed to, and therefore, some individuals might be at higher risk for mental health problems [7]. Some of the stressors that occur during a pandemic can be considered critical life events (e.g. death of loved ones and job loss) and require adjustment to changed life circumstances [8]. A lack of adjustment can lead to psychological distress, for example expressed in a change of one's psychological condition. This can include experiencing depressive and anxiety symptoms [9]. Furthermore, maladaptive adjustment to critical life events might eventually lead to full-blown mental disorders like adjustment disorders (AjD) or depression [10-12].

Some recommendations for interventions targeting psychological distress due to the COVID-19 pandemic have been made: Firstly, cognitive behavioural therapy (CBT), in particular the restructuring of thought patterns and cognitive thinking traps, as well as activity planning and relaxation techniques are considered suitable interventions [6, 13]. Secondly, digital aids such as internet-based self-help interventions are encouraged, as they do not require physical contact and are easily scalable [6, 14, 15].

The efficacy of internet-based self-help interventions for various psychological problems is established [16, 17]. However, internet-based interventions can differ in their design, especially in the degree of therapist support that they offer. While some internet-based interventions offer contact with a therapist (guided self-help) other interventions are completely automated (unguided self-help). Moreover, guided self-help interventions can differ in the intensity of provided contact. On the one hand, guided self-help programs yield higher effect-sizes and have higher retention rates than unguided self-help programs [18, 19]. On the other hand, unguided self-help programs have the advantage that they are less costly and better scalable [20]. One promising approach, possibly combining the benefits of both guided and unguided self-help programs, is the use of guidance on demand [21]. Guidance on demand implies that support from a therapist is only established when requested by a participant. An internet-based self-help program for increased self-criticism with guidance on demand showed promising results [22]. Nonetheless, an internet-based self-help program for symptoms of anxiety and/or depression based on problem-solving therapy with guidance on demand had the same effect as the unguided version of the same program [23]. Likewise, an internet-based self-help program for tinnitus-related distress based on CBT with guidance on demand did not differ in its effectiveness from the unguided version of that program [24].

To the best of our knowledge, there is no study that has evaluated an internet-based self-help intervention for psychological distress due to COVID-19 in the general population yet. However, an internet-based self-help intervention for patients diagnosed with COVID-19 experiencing psychological distress has been evaluated in a small randomized controlled trial (RCT) [25]. The internet-based self-help intervention consisted of audio-recorded instructions focusing on relaxation, self-care and a rising sense of security, which were uploaded online. Over a 2-week period, participants in the intervention group listened to the instructions via their mobile phone and performed a daily task, which took about 50 minutes. The intervention addressed COVID-19 patients with mild-to-moderate depression and/or anxiety symptoms. The average age of the 26 participants was 44.7 years; 62% were male and 38% were female. 92% of the participants experienced at least mild depression symptoms and 62% experienced at least mild anxiety symptoms. Participants in the intervention group showed a significant reduction in depression and anxiety symptoms compared to the control group [25].

Against this background, we developed an internet-based self-help intervention with guidance on demand called ROCO. This intervention specifically addresses individuals experiencing psychological distress due to the COVID-19 pandemic. Hence, the study aims to evaluate the efficacy and feasibility of the internet-based self-help program ROCO for people with psychological distress due to the COVID-19 pandemic.

Objectives {7}

The specific objectives of the study are:

(1) To evaluate the effects of the internet-based self-help program compared with a waiting control condition on:

- The primary outcome depressive symptoms

- Secondary outcomes such as anxiety and stress symptoms, well-being, embitterment and loneliness

(2) To evaluate the acceptance and user-friendliness of the internet-based self-help program and drawing conclusions for further developments of the program.

(3) To exploratory search for predictors, moderators and mediators for the efficacy of the program:

- e.g. optimism, age, severity of depressive symptoms and frequency of use of the program

Trial design {8}

The study is a parallel group RCT comparing an internet-based self-help intervention combined with care as usual (CAU) to a waiting control condition with only CAU. The study flowchart is displayed in Figure 1. Participants in the waiting control condition receive access to the intervention 3 weeks after the baseline questionnaire. Eligible participants are randomly allocated to one of the two conditions in a 1:1 allocation ratio.

The aim of the RCT is to show the superiority of the internet-based self-help intervention combined with CAU to only CAU at the 3-week post assessment. Additionally, there will be 2 follow-up measurements after 6, respectively 18 weeks after the baseline questionnaire. Since at the time of the follow-up measurements both groups have used the internet-based self-help intervention, the groups can no longer be compared. However, we use these follow-up measurements to assess the sustainability of potential treatment gains, i.e. to examine whether the short-term effects of the internet-based self-help intervention are maintained within groups. In addition, the follow-up measurements will be used to explore predictors of the sustainability of potential treatment effects.

Figure 1

Flowchart of the study design
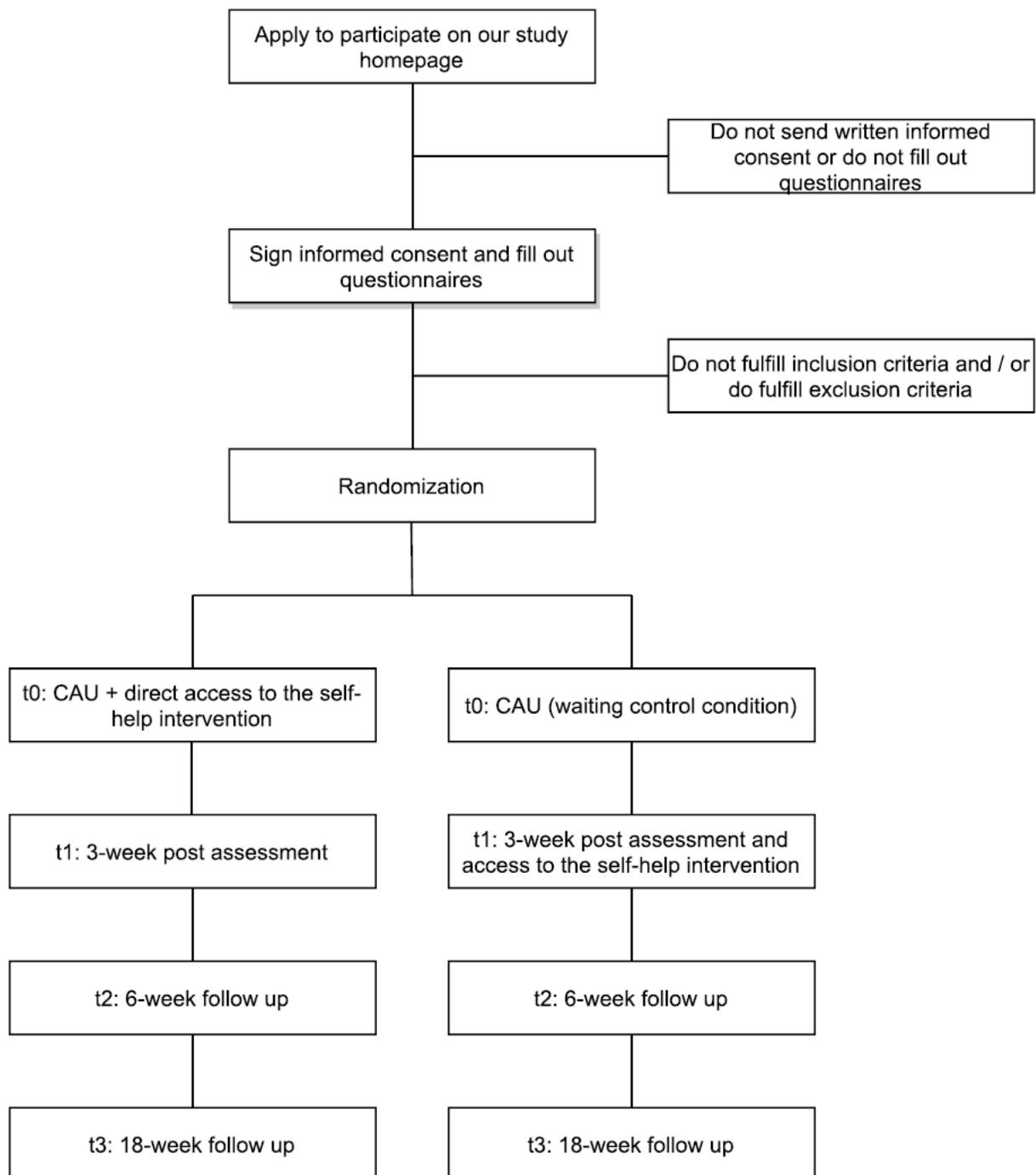
Methods: Participants, interventions and outcomes

Study setting {9}

The single study center is located at the University of Bern, Switzerland. All data is collected

online using questionnaires programmed in Qualtrics [28]. Data is collected in German-speaking

areas (i.e. Switzerland, Germany, Austria and Liechtenstein).

Eligibility criteria {10}

All interested persons must provide full written informed consent and are required to complete a

baseline-screening questionnaire prior to randomization to assess eligibility.

Inclusion criteria are:

1. To be at least 18 years old

2. To exceed a cut-off value of 4 points on the brief Patient Health Questionnaire (PHQ-9)

   [29]

3. To be able to specify an emergency address in the event of an acute crisis

4. To have access to the internet

5. To understand and master the German language to the degree that one understands the

   content and instructions of the study

Exclusion criteria are:

1. The presence of suicidal tendencies (Score ≥ 8 on the Suicide Behavior Questionnaire

   Revised (SBQ-R) [30]

2. A known diagnosis of a psychotic or bipolar disorder

Who will take informed consent? {26a}

Individuals interested in participating in the study can provide their e-mail address on the study

homepage. Subsequently, they receive an e-mail with the detailed study information and the

informed consent form. They are also asked to watch a video on the study homepage in which the study information is explained orally by the principal investigator. Individuals have the possibility to ask the study team questions about the study via e-mail. Written informed consent is obtained from individuals willing to participate in the study by the Principal Investigator.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Not applicable as no ancillary studies are performed.

Interventions

Explanation for the choice of comparators {6b}

The efficacy of the intervention is to be established. This is why we have chosen a waiting control condition as comparator. However, both the participants in the waiting control condition as well as in the intervention condition receive CAU, whereby CAU can range from no treatment at all to psychotherapy and/or drug therapy. Participants in the waiting control condition receive access to the internet-based self-help program after a waiting period of 3 weeks. We decided to give participants in the waiting control condition access to the program after only 3 weeks since, due to the pressing situation surrounding the COVID-19 pandemic, we wanted to give all participants access to psychological support as fast as possible. However, this has the implication that only short-term effects of the intervention can be assessed.

Intervention description {11a}

The intervention is a 3-week internet-based self-help program with guidance on demand called ROCO. The self-help program consists of 6 thematic modules including texts, videos, graphics, exercises and for each module a weekly task. The 6 thematic modules are supplemented by an introduction and a conclusion. For a detailed description, see Table 1. Furthermore, the self-help

program comprises a page with information on what to do in an acute crisis, including a list with

emergency contacts, as well as a page named *Toolbox,* where the weekly tasks are listed.

Participants also can track their symptoms on a page named *Mood-Tracker*.

Participants are encouraged to work through two of the 6 thematic modules per week. One

module takes between 40 to 80 minutes to complete. However, participants can determine the

timing and order of the modules themselves. The first module includes information about

possible psychological consequences and challenges concerning the situation surrounding

COVID-19. In the second module participants receive information concerning ways to deal with

difficult feelings that may arise due to the current situation. The third module focuses on

restructuring thought patterns and cognitive thinking traps and the fourth module on promoting

resilience and coping skills. The fifth module consists of information about sleep hygiene and

relaxation techniques. Finally, the last module addresses self-care and personal growth.

As the self-help program offers guidance on demand, participants have the possibility to contact

a psychologist, but there is no scheduled contact per se. Participants can require guidance via

chat function in the self-help program. They are informed that a psychologist will answer their

request within 3 working days. Otherwise, the self-help program is unguided.

Table 1

Outline of the content of the internet-based self-help program ROCO

Introduction	Information about the self-help program
1. Identifying consequences and challenges	Information about psychological distress/adjustment problems due to the COVID-19 pandemic, assessment of the current state (bodily sensations, positive and negative feelings), resource-oriented weekly task
2. Understanding own feelings	Information about feelings such as anxiety, helplessness, anger, sense of shame and sadness, strategies to cope with these feelings, acceptance-oriented weekly task
3. Changing the perspective	Information about the influence of thoughts, automatic thoughts, rumination and irrational beliefs, exercises to challenge own thinking patterns, weekly task on rumination
4. Strengthening resilience	Information about resilience and three possible ways of gaining resilience, namely coping, joie de vivre and optimism, exercises to promote these, resource-oriented weekly task
5. Finding rest	Information about sleep, sleep hygiene and relaxation techniques, progressive muscle relaxation as a weekly task
6. Taking care of oneself	Information about the concept of posttraumatic growth and the importance of pleasure, exercises of gratitude and mindfulness, resource-oriented weekly task
Conclusion	Information about the importance of practicing and transferring what has been learnt to daily life

Criteria for discontinuing or modifying allocated interventions {11b}

Since internet-based self-help is not suited as a treatment for acute suicidality, participants

reporting an acute crisis during treatment are referred to an appropriate treatment. This will be

recorded and reported as an adverse event.

Strategies to improve adherence to interventions {11c}

Participants have the possibility to enable reminders within the self-help program. They can

choose whether the reminder is sent via e-mail or text message after a certain time of inactivity.

In the reminder, participants are encouraged to log into the self-help program again. We have

further adopted a guidance on demand approach, since some form of support appears to increase

adherence [19].

Relevant concomitant care permitted or prohibited during the trial {11d}

Participants receiving the intervention, as well as participants in the waiting control condition are

allowed to start any concomitant treatment at any time during the trial. However, participants

must indicate at each measurement time whether they use concomitant psychological or

psychiatric treatment (e.g. psychotherapy or drug therapy).

Provisions for post-trial care {30}

 The University of Bern will provide insurance for any harm suffered as a result from this trial.

Outcomes {12}

All assessments are carried out online via self-observation questionnaires. The baseline

measurement is at t_0, the post-measurement t_1 is at 3 weeks, the first follow-up measurement t_2 is

at 6 weeks, and the second follow-up measurement t_3 is at 18 weeks after the baseline. Validated

German versions of the questionnaires are used. For an overview of all outcome measures and

corresponding measurement time points see Figure 2.

Primary outcome measure

Patient Health Questionnaire (PHQ-9). The primary outcome measure is the score of the

PHQ-9 [29]. The PHQ-9 is a 9-item measure assessing the severity of depressive symptoms. All

9 DSM-IV criteria for depression are scored on a scale from 0 = not at all to 5 = nearly every

day. A score of 5 represents a mild depression, a score of 10 a moderate depression, a score of 15 a moderately severe depression and a score of 20 a severe depression [31]. The PHQ-9 showed good internal consistency (Cronbach's alpha between 0.86 and 0.89) [32, 33].

Secondary outcome measures

Depression Anxiety Stress Scale (DASS-21). The DASS-21 is a short-form of the DASS and is used to assess depressive mood, anxiety and chronic stress during the past week [34]. The DASS-21 consists of 21 items which are answered on a scale from 0 = did not apply to me at all to 3 = applied to me very much or most of the time. The internal consistencies of the scores for depressive mood, for anxiety and for chronic stress (Cronbach's alpha = 0.88, 0.76 and 0.86) lie between satisfactory and good [35].

Suicide Behavior Questionnaire Revised (SBQ-R). The SBQ-R assesses suicidal experiences and behaviour [30]. The SBQ-R consists of 4 items which are not scaled equally. A total score of the 4 items is calculated. The total score can range from 3 to 18 whereas a score greater than or equal to 8 is considered the most useful cut-off score for suicide risk in a clinical sample [30]. This SBQ-R cut-off is also used as an indication for suicidal tendencies (safety outcome). The internal consistency of the SBQ-R is satisfactory (Cronbach's alpha = 0.72) [36].

12-Item Short-Form Health Survey (SF-12). The SF-12 assesses health-related quality of life and is the short version of the Medical Outcomes Study 36-Item Short-Form Health Survey [37]. The SF-12 consists of 12 items with varying answer format. There are two versions of the SF-12, one assessing the health-related quality of life over the past week and one assessing it over the past 4 weeks. In this study, the latter is used. From the 12 items of the SF-12, a Physical Component Score and a Mental Component Score can be calculated. The internal consistency of the subscales exceeds the recommended Cronbach's alpha level of 0.70 [38] .

Life Orientation Test Revised (LOT-R). The LOT-R is a 10-item scale assessing generalized optimism and pessimism [39] . The items are answered on a scale from 0 = strongly disagree to 4 = strongly agree. 3 items form the score for pessimism and 3 items the score for optimism, whereas 4 items are unscored as they are filler items. The internal consistency is satisfactory with a Cronbach's alpha of 0.69 for optimism and 0.68 for pessimism [40].

Bern Embitterment Inventory (BEI). The BEI is a 18-item questionnaire assessing embitterment, whereby embitterment can be understood as the feeling of being disadvantaged by others and fate [41, 42]. The items are answered on a scale from 0 = I do not agree to 4 = I agree. The internal consistency for the total embitterment score is good (Cronbach's alpha 0.89) [41]. In this study, the 6-item short version of the BEI is used [43].

General Self-Efficacy Scale (GSE). The GSE is a 10-item questionnaire assessing optimistic self-beliefs [44]. The items are answered on a scale from 1 = not at all true to 4 = exactly true. The internal consistency (Cronbach's alpha) for the total score ranges between .76 and .90 [44].

Self-report Measure for the assessment of emotion regulation skills (SEK-27). The SEK-27 assesses adaptive ways of coping with negative emotions [45]. The 27 items are answered on a scale from 0 = never to 4 = (almost) always. Two versions of the SEK-27 are available: a trait version assessing the coping with negative emotions in general and a prolonged state version assessing the coping with negative emotions over the last week. In this study, the latter is used. A total scale as well as the subscales attention, bodily awareness, clarity, understanding, regulation, acceptance, resilience, self-support and goal-oriented readiness for confrontation can be formed. The total scale of the prolonged state version has an excellent internal consistency (Cronbach's alpha = 0.90). The internal consistency of the subscales of the prolonged state version range from 0.72 to 0.81 [46].

UCLA Loneliness Scale (ULS). The ULS is a measure assessing one's subjective feeling of loneliness [47]. The items are answered on a scale from 1 = never to 4 = often. The original version of the ULS consists of 20 items and has an internal consistency (Cronbach's alpha) ranging from 0.82 to 0.92 [47]. In this study, a 9-item version of the ULS is used.

Connor-Davidson Resilience Scale (CD-RISC). The CD-RISC assesses resilience [48]. Items are answered on a scale from 0 = not true at all to 4 = true nearly all of the time. In this study, the 10-item version of the CD-RISC is used. The 10-item version has a good internal consistency (Cronbach's alpha) of 0.84 [49].

Client Satisfaction Questionnaire-8 (CSQ-8). The CSQ-8 assesses the satisfaction of the participants with the intervention [50]. The CSQ-8 consists of 8 items which are answered on a scale from 1 = poor to 4 = excellent. Since the CSQ-8 measures the satisfaction with the intervention, it can only be used after the intervention phase. THE CSQ-8 has an excellent internal consistency (Cronbach's alpha) ranging from 0.87 to 0.93 [51].

System Usability Scale (SUS). The SUS is used to assess the usability of a system such as mobile devices, websites and applications [52]. The 10 items of the SUS are answered on a scale from 1 = strongly disagree to 5 = strongly agree. A score between 0 and 100 can be calculated, indicating the usability of a system, in this case the internet-based self-help program. Since the SUS measures the system usability of the internet-based self-help program, it can only be used after the intervention phase. The English version of the SUS has an excellent internal consistency (Cronbach's alpha) ranging from = 0.91 to 0.92 [53, 54].

Predictors and moderators

Demographic variables. Demographic variables include sex, age, country of residence, civil status, housing situation, current childcare situation, education, employment situation (before and

during COVID-19 pandemic), income (before and during COVID-19 pandemic), current

everyday working life, psychiatric medical history, concomitant psychological/psychiatric

treatment and COVID-19 specific questions (e.g., belonging to a risk group, own illness or

instances of deceased family members due to the pandemic).

Adherence. The intensity and frequency of use of the self-help program is measured by

indicators collected within the self-help program such as percentage of accessed pages or number

of logins.

Participant timeline {13}

Figure 2

SPIRIT figure, schedule of enrolment, interventions and assessments

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			
			Intervention / Waiting period			
TIMEPOINT	t_0	0	0	t_1	t_2	t_3
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
ROCO direct access			●——————●			
Waiting control group				●———●		
ASSESSMENTS:						
Primary outcome measure						
Patient Health Questionnaire (PHQ-9)	X			X	X	X
Secondary outcome measures						
Depression Anxiety Stress Scale (DASS-21)	X			X	X	X
Suicide Behavior Questionnaire Revised (SBQ-R)	X			X	X	X
12-Item Short-Form Health Survey (SF-12)	X			X	X	X
Life Orientation Test Revised (LOT-R)	X			X	X	X
Bern Embitterment Inventory (BEI)	X			X	X	X
General Self-Efficacy Scale (GSE)	X			X	X	X
Self-report Measure for the assessment of emotion regulation skills (SEK-27)	X			X	X	X
UCLA Loneliness Scale (ULS)	X			X	X	X
Connor-Davidson Resilience Scale (CD-RISC)	X			X	X	X
Client Satisfaction Questionnaire-8 (CSQ-8)				X	X	
System Usability Scale (SUS)				X	X	
Predictors and mediators						
Demographic variables	X					
Concomitant psychological/psychiatric treatment	X			X	X	X
Adherence			●——————●	●———●		

Sample size {14}

To specify the sample size needed for the different analyses, we conducted a power analysis based on a probability level of 0.05 and a power of 0.80 with G*Power [55] for a repeated-measures ANOVA with a within-between-interaction. To test the efficacy of the self-help program compared to the control condition, we expected a small-to-medium between group effect size of $d = 0.35$ and a correlation between the factors of at least $r = 0.4$. The expected effect size is based on the results of meta-analyses on the effectiveness of unguided internet-based self-help programs targeting depressive symptoms [17, 56]. We decided to base the expected effect size on unguided internet-based self-help programs as it is yet to be determined if a guidance on demand approach yields higher effect sizes than unguided self-help [23, 24] . Power analysis indicated a necessary sample size of 80 individuals. In consideration of a possible attrition rate between 5.4% to 45.5% at post-assessment, we aim to recruit between 80 and 120 participants at baseline [17].

Recruitment {15}

Participants are recruited from the general population via the study web page. This study web page is advertised on various websites, internet forums and social media. The study web page includes information about the self-help program and the study. People interested in participating can leave their e-mail address on the study homepage and will then be sent the detailed participant information per e-mail.

Assignment of interventions: allocation

Sequence generation {16a}

Eligible participants will be randomly allocated to either the intervention or the waiting control

condition with a 1:1 allocation ratio as per a computer generated randomization schedule using randomly permuted block sizes by Randomization.com [57].

Concealment mechanism {16b}

The allocation schedule was generated by an independent researcher and is unknown to the investigators. Allocation takes place after the baseline assessment has been completed. Since the allocated condition is not known until the interested individual has been recruited into the trial, allocation concealment is ensured.

Implementation {16c}

All interested individuals who give written informed consent for participation and who fulfil all the inclusion criteria and none of the exclusion criteria will be randomized. Staff members responsible for recruitment and data management will ask the independent researcher to randomize respective individuals. In return, the independent researcher informs the staff members per e-mail about the allocation. Finally, the staff members inform the individual about the assigned condition per e-mail.

Assignment of interventions: Blinding

Who will be blinded {17a}

The staff members are not blinded to the allocation. However, all assessments are performed online with self-report questionnaires. Since participants either receive direct access to the self-help program or have a waiting period, participants are neither blinded to their allocation.

Procedure for unblinding if needed {17b}

Not applicable since no blinding is performed.

Data collection and management

Plans for assessment and collection of outcomes {18a}

All data is assessed online by means of questionnaires programmed in Qualtrics [28]. In addition, data on the use of the self-help program (e.g. number of logins or processed pages) is collected within the self-help program.

Plans to promote participant retention and complete follow-up {18b}

The participants are asked by e-mail to complete the online questionnaires. If participants fail to complete a questionnaire, they will be reminded by e-mail to do so: For post measurement, they will be reminded after 5 and 10 days and for follow-up measurements after 7 and 14 days. All participants are asked to complete the online questionnaire at each point of measurement, regardless of protocol adherence or any previously uncompleted online questionnaires.

Data management {19}

Data quality is ensured through several mechanisms, including referential data rules, valid values, range checks and consistency checks. The option to choose a value from a list of valid codes and a description of the meaning of the code will be available where applicable. Checks are applied at the time of data entry into a specific field. All data collected is stored on a firewall-encrypted back-upped server of the University of Bern with strictly regulated access only for researchers directly involved in the study.

Confidentiality {27}

All data concerning participant information will be stored in locked file cabinets only accessible for staff members. All collected data will only be traceable by a code. All files containing names or other personal identifiers, such as the informed consent forms, will be stored separately from

data containing this code number.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable since no biological specimens are used.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

We will use linear mixed models with time (pre versus post-intervention measures) as a within-group-factor and study condition (immediate access versus control condition) as a between-group-factor to evaluate the efficacy of the internet-based self-help intervention. This primary analysis will be performed using the data from the baseline and the 3-week post assessment. To analyze the stability of the short-term effects of the internet-based self-help intervention, we will conduct within-group analyses using repeated measures ANOVA (pre-intervention, post-intervention and follow-up measures) and paired t-tests when comparing only two time points. Moreover, we will exploratory analyze possible predictors, mediators and moderators for the relationship between the internet-based self-help program and the outcomes. The significance level is set at 5%. Analyses will be conducted using SPSS and R.

Interim analyses {21b}

Not applicable since no interim analyses are planned.

Methods for additional analyses (e.g. subgroup analyses) {20b}

Not applicable since no additional analyses such as subgroup analyses are planned.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Statistical analyses will be carried out according to the intention-to-treat approach and therefore will include all randomized participants. The extent of missing data will be analyzed. We will explore missing data patterns and determine the type of missing data (missing completely at random, missing at random, not missing at random). We will use multiple imputation to substitute missing values and will conduct sensitivity analyses for both the datasets with and without the imputed data.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

There are no plans for granting public access to the full protocol, participant-level dataset and statistical code.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

There is no trial steering committee. The composition of the coordinating centre is as follows:

- Principal Investigator: HZ
    - Design and conduct of the study
    - Publication of study reports
    - Preparation of protocol and revisions and Case Report Forms
- Co-Principal Investigator: TB
    - Design and conduct of the study
    - Publication of study reports
    - Preparation of protocol and revisions and Case Report Forms

- PhD students: NB and JH

  o Supporting the Principal and Co-principal Investigator in all the above

  responsibilities

  o Data entry and management

  o Recruitment of participants

Composition of the data monitoring committee, its role and reporting structure {21a}

As to the best of our knowledge, the internet-based self-help program in itself does not bear risks

for the participants. Therefore, a data monitoring committee is not required. The Principal-

Investigator, the Co-Principal-Investigator and the PhD students warrant for data and participant

safety.

Adverse event reporting and harms {22}

In this trial, adverse events are defined as unintended negative developments in the participants,

which may occur at the time of the use of the internet-based self-help program, but do not have

to be causally related to its use. Those unintended negative developments in the participants

include acute suicidality and hospitalization. Such adverse events and the corresponding actions

taken will be documented in the case report form.

Frequency and plans for auditing trial conduct {23}

The research management of the Faculty of Human Sciences at the University of Bern, an

independent research control unit, warrants the auditing. There will be on site monitoring visits

on a regular basis. The monitoring visits are documented in a monitoring report form. The data

monitoring committee controls study procedures such as the site progress and enrollment,

obtaining participant informed consent, randomization or the reporting of adverse events.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Important protocol amendments will be reported to the relevant parties (i.e. the Cantonal Ethics committee Bern, the trial participants and trial registries) by e-mail. Substantial amendments are only implemented after approval of the Cantonal Ethics committee Bern. All non-substantial amendments are communicated to the Cantonal Ethics committee Bern within the Annual Safety Report.

Dissemination plans {31a}

Trial participants and the general population are informed about the results of the study by means of a results report.

Discussion

The internet-based self-help program ROCO is, to the best of our knowledge, one of the first internet-based self-help programs specifically developed for the treatment of psychological distress due to the situation surrounding the COVID-19 pandemic. The results will give insight into the efficacy and acceptance of an internet-based self-help program in the context of COVID-19 pandemic related psychological distress. Moreover, the results will contribute to the further adaption of the self-help program. In light of possible multiple waves and future pandemics, it is important to investigate the effectiveness of such psychological interventions as mental health resources might be strained.

Limitations of this study include that only short-term effects of the internet-based self-help program can be determined, since the waiting control condition already receives access to the self-help program after 3 weeks.

Trial status

Trial start date: May 2020.

Currently recruiting (N = 99, January 2021)

Approximate date when recruitment will be completed: April 2021.

Version 3: 28. January 2021

Abbreviations

AjD: adjustment disorder; BEI: Bern Embitterment Inventory; CAU: care as usual; CBT: cognitive behavioural therapy; CD-RISC: Connor-Davidson-Resilience Scale; COVID-19: Coronavirus 19; CSQ-8: Client Satisfaction Questionnaire-8; DASS-21: Depression Anxiety Stress Scale; GSE: General Self-Efficacy Scale; LOT-R: Life Orientation Test Revised; PHQ-9: Patient Health Questionnaire; RCT: randomized controlled trial; SARS: severe acute respiratory syndrome; SBQ-R: Suicide Behavior Questionnaire Revised; SEK-27: Self-report Measure for the assessment of emotion regulation skills; SF-12: 12-Item Short-Form Health Survey; SUS: System Usability Scale; ULS: UCLA loneliness Scale

Acknowledgements

We thank Céline Bieri for supporting the data management and organization of e-mail schedules.

Authors' contributions {31b}

NB participated in the design of the study and the development and programming of the self-help program and drafted the manuscript. JH participated in the design of the study and the development and programming of the self-help program. TB and HZ participated in the design of the study and HZ conceived the study. All authors read and approved the final manuscript.

Funding {4}

This study is entirely funded by the University of Bern. The funding body (University of Bern) played no role in the design of the study, the collection, analysis and interpretation of data or in writing the manuscript. However, the trial sponsor is the principal investigator of the study (sponsor investigator).

Availability of data and materials {29}

The Principal Investigator, the Co-Principal Investigator and the PhD students have access to the full data sets. All data collected is stored on a firewall-encrypted back-upped server of the University of Bern with strictly regulated access only for researchers directly involved in the study.

Ethics approval and consent to participate {24}

Ethical approval has been obtained by the Cantonal Ethics Committee Bern (BASEC2020-00990). The study is registered with ClinicalTrials.gov (NCT04380909). Informed consent will be obtained from all participants in this study.

Consent for publication {32}

Not applicable.

Competing interests {28}

The authors declare that they have no competing interests.

References

1. Sritharan J, Sritharan A. Emerging mental health issues from the novel Coronavirus (COVID-19) pandemic. Journal of Health and Medical Sciences. 2020;3(2).

2. Lau JT, Yang X, Pang E, Tsui H, Wong E, Wing YK. SARS-related perceptions in Hong Kong. Emerging infectious diseases. 2005;11(3):417.

3. Qiu J, Shen B, Zhao M, Wang Z, Xie B, Xu Y. A nationwide survey of psychological distress among Chinese people in the COVID-19 epidemic: implications and policy recommendations. General psychiatry. 2020;33(2).

4. Wissmath B, Mast FW, Kraus F, Weibel D. Understanding the psychological impact of the COVID-19 pandemic and containment measures: an empirical model of stress. medRxiv. 2020.

5. Rajkumar RP. COVID-19 and mental health: A review of the existing literature. Asian journal of psychiatry. 2020:102066.

6. Wang C, Pan R, Wan X, Tan Y, Xu L, Ho CS, et al. Immediate psychological responses and associated factors during the initial stage of the 2019 coronavirus disease (COVID-19) epidemic among the general population in China. International journal of environmental research and public health. 2020;17(5):1729.

7. Boyraz G, Legros DN. Coronavirus Disease (COVID-19) and Traumatic Stress: Probable Risk Factors and Correlates of Posttraumatic Stress Disorder. Journal of Loss and Trauma. 2020:1-20.

8. Holmes TH, Rahe RH. The social readjustment rating scale. Journal of psychosomatic research. 1967.

9. Ridner SH. Psychological distress: concept analysis. Journal of advanced nursing. 2004;45(5):536-45.

10. Bachem R, Casey P. Adjustment disorder: A diagnosis whose time has come. Journal of affective disorders. 2018;227:243-53.

11. Maercker A, Einsle F, Köllner V. Adjustment disorders as stress response syndromes: a new diagnostic concept and its exploration in a medical sample. Psychopathology. 2007;40(3):135-46.

12. Kendler KS, Karkowski LM, Prescott CA. Causal relationship between stressful life events and the onset of major depression. American Journal of Psychiatry. 1999;156(6):837-41.

13. Halder S. COVID-19: Psychological Impact and Psychotherapeutic Intervention. EC Psychology and Psychiatry. 2020;9:32-5.

14. Rosen CS, Glassman LH, Morland LA. Telepsychotherapy during a pandemic: A traumatic stress perspective. Journal of Psychotherapy Integration. 2020;30(2):174.

15. Wind TR, Rijkeboer M, Andersson G, Riper H. The COVID-19 pandemic: The 'black swan'for mental health care and a turning point for e-health. Internet interventions. 2020;20.

16. Andersson G, Titov N. Advantages and limitations of Internet-based interventions for common mental disorders. World Psychiatry. 2014;13(1):4-11.

17. Cuijpers P, Donker T, Johansson R, Mohr DC, van Straten A, Andersson G. Self-guided psychological treatment for depressive symptoms: a meta-analysis. PloS one. 2011;6(6):e21274.

18. Andersson G, Cuijpers P. Internet-based and other computerized psychological treatments for adult depression: a meta-analysis. Cognitive behaviour therapy. 2009;38(4):196-205.

19. Richards D, Richardson T. Computer-based psychological treatments for depression: a systematic review and meta-analysis. Clinical psychology review. 2012;32(4):329-42.

20. Baumeister H, Reichler L, Munzinger M, Lin J. The impact of guidance on Internet-based mental health interventions—A systematic review. internet Interventions. 2014;1(4):205-15.

21. Berger T, Caspar F, Richardson R, Kneubühler B, Sutter D, Andersson G. Internet-based treatment of social phobia: a randomized controlled trial comparing unguided with two types of guided self-help. Behaviour research and therapy. 2011;49(3):158-69.

22. Krieger T, Reber F, von Glutz B, Urech A, Moser CT, Schulz A, et al. An internet-based compassion-focused intervention for increased self-criticism: A randomized controlled trial. Behavior therapy. 2019;50(2):430-45.

23. Kleiboer A, Donker T, Seekles W, van Straten A, Riper H, Cuijpers P. A randomized controlled trial on the role of support in Internet-based problem solving therapy for depression and anxiety. Behaviour research and therapy. 2015;72:63-71.

24. Rheker J, Andersson G, Weise C. The role of "on demand" therapist guidance vs. no support in the treatment of tinnitus via the internet: a randomized controlled trial. Internet Interventions. 2015;2(2):189-99.

25. Wei N, Huang B-c, Lu S-j, Hu J-b, Zhou X-y, Hu C-c, et al. Efficacy of internet-based integrated intervention on depression and anxiety symptoms in patients with COVID-19. Journal of Zhejiang University Science B. 2020:1.

26. Bachem R, Maercker A. Self-help interventions for adjustment disorder problems: A randomized waiting-list controlled study in a sample of burglary victims. Cognitive behaviour therapy. 2016;45(5):397-413.

27. Moser C, Bachem R, Berger T, Maercker A. ZIEL: Internet-based self-help for adjustment problems: Results of a randomized controlled trial. Journal of clinical medicine. 2019;8(10):1655.

28. Qualtrics. www.qualtrics.com. Accessed: 9 July 2020

29. Löwe B, Spitzer RL, Zipfel S, Herzog W. Gesundheitsfragebogen für Patienten (PHQ-D). Komplettversion und Kurzform. Testmappe mit Manual, Fragebögen, Schablonen. 2. Auflage. . Karlsruhe: Pfizer; 2002 01/01. 90-3 p.

30. Osman A, Bagge CL, Gutierrez PM, Konick LC, Kopper BA, Barrios FX. The Suicidal Behaviors Questionnaire-Revised (SBQ-R): validation with clinical and nonclinical samples. Assessment. 2001;8(4):443-54.

31. Kroenke K, Spitzer RL. The PHQ-9: a new depression diagnostic and severity measure. Psychiatric annals. 2002;32(9):509-15.

32. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. Journal of general internal medicine. 2001;16(9):606-13.

33. Gräfe K, Zipfel S, Herzog W, Löwe B. Screening psychischer Störungen mit dem "Gesundheitsfragebogen für Patienten (PHQ-D)". Diagnostica. 2004;50(4):171-81.

34. Lovibond SH, Lovibond PF. Manual for the Depression Anxiety Stress Scales. Sydney: Psychology Founation of Australia; 1995.

35. Nilges P, Essau C. Die Depressions-Angst-Stress-Skalen. Der Schmerz. 2015;29(6):649-57.

36. Glaesmer H, Kapusta ND, Teismann T, Wagner B, Hallensleben N, Spangenberg L, et al. Psychometrische Eigenschaften der deutschen Version des Suicide Behaviors Questionnaire Revised (SBQ-R). PPmP-Psychotherapie· Psychosomatik· Medizinische Psychologie. 2018;68(08):346-52.

37. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care. 1996;34(3):220-33.

38. Morfeld M, Kirchberger I, Bullinger M. SF-36. Fragebogen zum Gesundheitszustand. Göttingen: Hogrefe; 2011.

39. Glaesmer H, Hoyer J, Klotsche J, Herzberg PY. Die deutsche version des Life-Orientation-Tests (LOT-R) zum dispositionellen Optimismus und Pessimismus. Zeitschrift für Gesundheitspsychologie. 2008;16(1):26-31.

40. Herzberg PY, Glaesmer H, Hoyer J. Separating optimism and pessimism: a robust psychometric analysis of the revised Life Orientation Test (LOT-R). Psychol Assess. 2006;18(4):433-8.

41. Znoj H. BVI. Berner Verbitterungs-Inventar. Göttingen: Hogrefe; 2008.

42. Znoj H, Abegglen S, Buchkremer U, Linden M. The embittered mind. Journal of individual differences. 2016.

43. Znoj H, Schnyder U. Verbitterungsfragebogen Kurzversion. Bern: University of Bern; 2014.

44. Jerusalem M, Schwarzer R. SWE. Skala zur allgemeinen Selbstwirksamkeitserwartung [Verfahrensdokumentation aus PSYNDEX Tests-Nr. 9001003, Autorenbeschreibung und Fragebogen]. 2003. In: Elektronisches Testarchiv [Internet]. Trier: ZPID. Available from: https://doi.org/10.23668/psycharchives.307.

45. Berking M, Znoj H. SEK-27. Fragebogen zur standardisierten Selbsteinschätzung emotionaler Kompetenzen [Verfahrensdokumentation aus PSYNDEX Tests-Nr. 9005957, Fragebogen und Auswertungsanweisung]. 2011 ed. (Hrsg.) ETTZ, editor: In Leibniz-Zentrum für Psychologische Information und Dokumentation (ZPID).

46. Berking M, Znoj H. Entwicklung und Validierung eines Fragebogens zur standardisierten Selbsteinschätzung emotionaler Kompetenzen (SEK-27). Zeitschrift für Psychiatrie, Psychologie und Psychotherapie. 2008;56(2):141-53.

47. Döring N, Bortz J. Psychometrische Einsamkeitsforschung: Deutsche Neukonstruktion der UCLA Loneliness Scale. Diagnostica. 1993.

48. Connor KM, Davidson JR. Development of a new resilience scale: The Connor-Davidson resilience scale (CD-RISC). Depression and anxiety. 2003;18(2):76-82.

49. Sarubin N, Gutt D, Giegling I, Bühner M, Hilbert S, Krähenmann O, et al. Erste Analyse der psychometrischen Eigenschaften und Struktur der deutschsprachigen 10-und 25-Item Version der Connor-Davidson Resilience Scale (CD-RISC). Zeitschrift für Gesundheitspsychologie. 2015.

50. Attkisson CC, Zwick R. The client satisfaction questionnaire. Psychometric properties and correlations with service utilization and psychotherapy outcome. Eval Program Plann. 1982;5(3):233-7.

51. Schmidt J, Lamprecht F, Wittmann W. Zufriedenheit mit der stationären Versorgung. Entwicklung eines Fragebogens und erste Validitätsuntersuchungen. PPmP: Psychotherapie Psychosomatik Medizinische Psychologie. 1989.

52. Brooke J. SUS: a "quick and dirty'usability. Usability evaluation in industry. 1996:189.

53. Lewis JR, Sauro J, editors. The Factor Structure of the System Usability Scale2009; Berlin, Heidelberg: Springer Berlin Heidelberg.

54. Bangor A, Kortum PT, Miller JT. An empirical evaluation of the system usability scale. Intl Journal of Human–Computer Interaction. 2008;24(6):574-94.

55. Faul F, Erdfelder E, Buchner A, Lang A-G. Statistical power analyses using G* Power 3.1: Tests for correlation and regression analyses. Behavior research methods. 2009;41(4):1149-60.

56. Karyotaki E, Riper H, Twisk J, Hoogendoorn A, Kleiboer A, Mira A, et al. Efficacy of self-guided internet-based cognitive behavioral therapy in the treatment of depressive symptoms: a meta-analysis of individual participant data. JAMA psychiatry. 2017;74(4):351-9.

57. Randomization.com. http://www.randomization.com. Accessed: 9 July 2020

2.5 Article 5: Effects of an internet-based self-help intervention for psychological distress due to COVID-19: Results of a randomized controlled trial

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Effects of an internet-based self-help intervention for psychological distress due to COVID-19: results of a randomized controlled trial

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Abstract

Background: The COVID-19 pandemic and its far-reaching impact on physical and mental health generate high demand and, accordingly, a great need for treatment opportunities that promote well-being and manage psychological distress. Internet-based interventions are particularly suitable for this purpose. They are easily scalable, readily accessible, and the online format allows for adherence to social distancing. For this reason, we developed an internet-based self-help intervention called ROCO to address psychological distress due to the COVID-19 pandemic. This randomized controlled trial aimed to examine the efficacy of the ROCO intervention.

Methods: A total of 107 German-speaking adults with at least mild depressive symptoms were randomized either to the intervention group with direct access to the three-week ROCO intervention plus care as usual or the waiting control group receiving care as usual. Primary outcome (depressive symptoms) and secondary outcomes (stress, anxiety, resilience, emotion regulation, health-related quality of life, embitterment, loneliness, optimism, and self-efficacy) were assessed pre- and post-treatment and at a 6-week follow-up using self-report questionnaires (e.g. Patient Health Questionnaire-9 for depressive symptoms).

Results: The average age was 40.36 years (SD = 14.59) and 81.3% of participants were female. The intervention did not significantly reduce primary depressive symptoms (between-group effect size: $d = 0.04$) and secondary outcomes such as anxiety and stress symptoms (between-group effect size: $d = -0.19$). However, the intervention led to a significant increase in emotion regulation skills (between-group effect $d = 0.35$) and resilience (between-group effect $d = 0.38$).

Conclusions: The internet-based self-help intervention cannot be recommended for the purpose of reducing depressive symptoms. However, the increase in emotion regulation skills and resilience suggest that the intervention may be suitable for preventive purposes, like

improving overall coping with psychological distress or potential stressors. Future research is needed to examine for whom and how the intervention is most effective.

Keywords: Coronavirus, COVID-19, Depression, Internet-based self-help, Psychological distress

Introduction

In December 2019, the first cases of pneumonia of unknown origin occurred in Wuhan, China. On March 11, 2020, the World Health Organization (WHO) declared the outbreak of the novel coronavirus disease 2019 (COVID-19) as a global pandemic, and as of July 2020, more than 10 million COVID-19 cases were reported worldwide . In addition to the threat to physical health, the COVID-19 outbreak may also negatively affect mental health. Research at the onset of the COVID-19 pandemic has already indicated that symptoms of depression, anxiety, and self-reported stress have increased in the general population (Rajkumar, 2020; Wang et al., 2020). Meanwhile, various studies point towards an increase in depression and anxiety symptoms in the general population (Luo et al., 2020; Xiong et al., 2020). Moreover, in a study comparing the prevalence of depression symptoms before and during the COVID-19 pandemic in the U.S. general population, more than a tripling of the prevalence was found (Ettman et al., 2020). A continuation of this rise in the level of depression symptoms can be expected, since ongoing restrictions such as social distancing measures lead to isolation and loneliness (Beutel et al., 2017; Dozois, 2020). Preliminary evidence supports this assumption (de Quervain et al., 2020). An online survey in Switzerland showed an increase in psychological distress from the first to the second COVID-19 wave in the general population. For example, during the first COVID-19 wave in April 2020, 9% of respondents reported severe depression symptoms, compared to 18% during the second COVID-19 wave in November 2020 (de Quervain et al., 2020). However, due to the method of data collection, these results should be considered with caution.

Since the COVID-19 pandemic appears to be associated with high levels of psychological distress in the general population, measures should be taken to diminish and prevent further negative mental health impacts. Accordingly, considering the potential increase in demand for psychological support and a continued requirement for social

distancing, easily accessible psychological interventions aiming to reduce COVID-19 related psychological distress are urgently needed (Luo et al., 2020; Xiong et al., 2020).

Information on the development and implementation of psychological interventions during the COVID-19 pandemic is still scarce. However, cognitive behavioral therapy (CBT) focusing on identifying and restructuring thought patterns and traps, relaxation techniques, and activity scheduling has been recommended (Halder, 2020; Wang et al., 2020). Furthermore, digital aids such as internet-based self-help interventions were found to be particularly suitable for the treatment of psychological distress under the given circumstances since they do not require direct on-site contact and are easily scalable (Halder, 2020; Soklaridis et al., 2020; Wang et al., 2020; Wind et al., 2020). Internet-based self-help interventions have proven to be an effective treatment option for various psychological problems, such as depressive symptoms (Andersson & Titov, 2014; Cuijpers et al., 2011).

To date, only a few studies have addressed psychological interventions targeting COVID-19 related psychological distress. In randomized controlled trials (RCT's), so far primarily psychological interventions for patients diagnosed with COVID-19 have been evaluated (Liu et al., 2020; Sotoudeh et al., 2020; Wei et al., 2020). For example, in an RCT, progressive muscle relaxation training over a period of 5 days effectively reduced anxiety and improved sleep quality in patients diagnosed with COVID-19 (Liu et al., 2020). Likewise, in a small RCT, a four-session face-to-face crisis intervention including relaxation, cognitive and metacognitive techniques, and techniques to increase resilience significantly reduced stress, anxiety, and depression in patients diagnosed with COVID-19 (Sotoudeh et al., 2020). With respect to internet-based self-help interventions for COVID-19 related psychological distress, Wei et al. (2020) evaluated the efficacy of an internet-based self-help intervention for patients diagnosed with COVID-19 experiencing psychological distress in a small RCT. The 2-week intervention consisting of breath relaxation training, mindfulness, and self-soothing skills has proven to reduce symptoms of anxiety and depression (Wei et al., 2020). Moreover, three

studies evaluated internet-based self-help interventions targeting COVID-19 related psychological distress in the general population. In their pragmatic RCT, Al-Alawi et al. (2021) found preliminary evidence that a 6-week internet-based intervention consisting of weekly online sessions based on CBT and acceptance and commitment therapy (ACT) with a certified psychotherapist significantly reduced symptoms of anxiety and depression. In addition, the control group receiving an internet-based self-help intervention (weekly newsletter based on CBT and ACT) also showed improvement in anxiety and depression. However, the online therapy sessions were found to be superior (Al-Alawi et al., 2021). Wahlund et al. (2021) evaluated a 3-week internet-based self-help intervention for dysfunctional worry related to COVID-19. The CBT-based intervention significantly reduced COVID-19 related worry and improved other outcomes such as mood and insomnia (Wahlund et al., 2021). In a pilot RCT, Aminoff et al. (2021) evaluated a tailored internet-based CBT intervention for psychological distress associated with the COVID-19 pandemic. During the 7-week intervention, participants worked on 7 out of 16 modules selected for them based on a screening and clinical interview. Participants received support from a therapist. The intervention significantly reduced depression and other outcomes such as anxiety and stress symptoms (Aminoff et al., 2021).

Based on this background, we conducted an RCT to evaluate the efficacy of an internet-based self-help intervention for psychological distress due to COVID-19 in the general population. The intervention condition was compared to a waiting control condition with both conditions receiving care as usual (CAU). We hypothesized that the 3-week intervention called "ROCO" would lead to greater reduction of depression symptoms (primary outcome measure) and anxiety and stress symptoms (secondary outcome measures). Furthermore, we hypothesized that the intervention in addition to CAU would lead to greater beneficial effects on well-being, optimism, embitterment, loneliness, optimistic self-beliefs,

emotion regulation skills, and resilience (secondary outcome measures) compared to CAU

alone. We expected the effects to be stable in the 6-week follow-up.

Methods

Study design

In this parallel group RCT, an immediate treatment group receiving direct access to

the 3-week internet-based self-help intervention was compared with a waiting control group.

Both groups received CAU. Participants in the waiting control group were given access to the

internet-based self-help intervention after 3 weeks. The immediate treatment group was

followed up 6 weeks after randomization to evaluate the maintenance of potential treatment

effects. We aimed to be able to detect small-to-medium between-group effect sizes of $d =$

0.35, since smaller effect sizes were considered clinically irrelevant (Donker et al., 2009). A

power analysis with an α error level of 0.05 and a power (1-β) of 0.80 indicated a necessary

sample size of at least 40 participants per group.

The Ethics Committee of the Canton of Bern approved the protocol of this study, and

the trial was registered on ClinicalTrials.gov (NCT04380909). However, there is a slight

deviation from the study protocol, as data from a second, 18-week, follow-up will be

published at a later time due to the pressing nature of the topic (Brog et al., 2021).

Participants

Recruitment of German-speaking participants took place between April 2020 and

February 2021, mainly through newspaper articles and internet self-help forums. All

interested participants first visited our study website (https://selfhelp.psy.unibe.ch/roco/).

Participants who registered on the study website subsequently received the study information.

After returning a written informed consent form signed by the participant, participants were

asked to complete an online baseline assessment. The online baseline assessment consisted of

the outcome measure questionnaires, questions concerning socio-demographic variables,

previous or present psychological treatment, and ongoing medication intake for psychological

problems. Eligibility for participation in the study was determined based on this baseline assessment.

Criteria for inclusion were *(a)* to be at least 18 years old, *(b)* to have access to the internet, *(c)* to have sufficient knowledge of the German language, *(d)* to be able to specify an emergency address in the event of an acute crisis, and *(e)* to exceed a cut-off value of 4 points on the Patient Health Questionnaire (PHQ-9: Löwe et al., 2002), which is interpreted as the presence of mild depressive symptoms. Criteria for exclusion were *(a)* the presence of suicidal tendencies (Score ≥ 8 on the Suicide Behavior Questionnaire Revised (SBQ-R); Osman et al., 2001) and *(b)* a known diagnosis of a psychotic or bipolar disorder.

A detailed description of the participant flow is shown in Fig. 1. A total of 26 participants had to be excluded after they filled out the baseline assessment, mainly due to present suicidal tendencies *(n = 15)* and falling below the PHQ-9 cut-off *(n = 8)*. Three participants fulfilled both exclusion criteria (suicidal tendencies and known diagnosis of a psychotic or bipolar disorder). A total of 107 participants fulfilled all the inclusion criteria and none of the exclusion criteria and were randomized to one of the two study groups in a 1:1 allocation ratio. Randomization was performed using a computer-generated randomization schedule by Randomization.com (Dallal, 2007, August 3). The allocation list was concealed from the investigators and participants.

Figure 1

Selection, randomization, and flow of participants throughout the trial
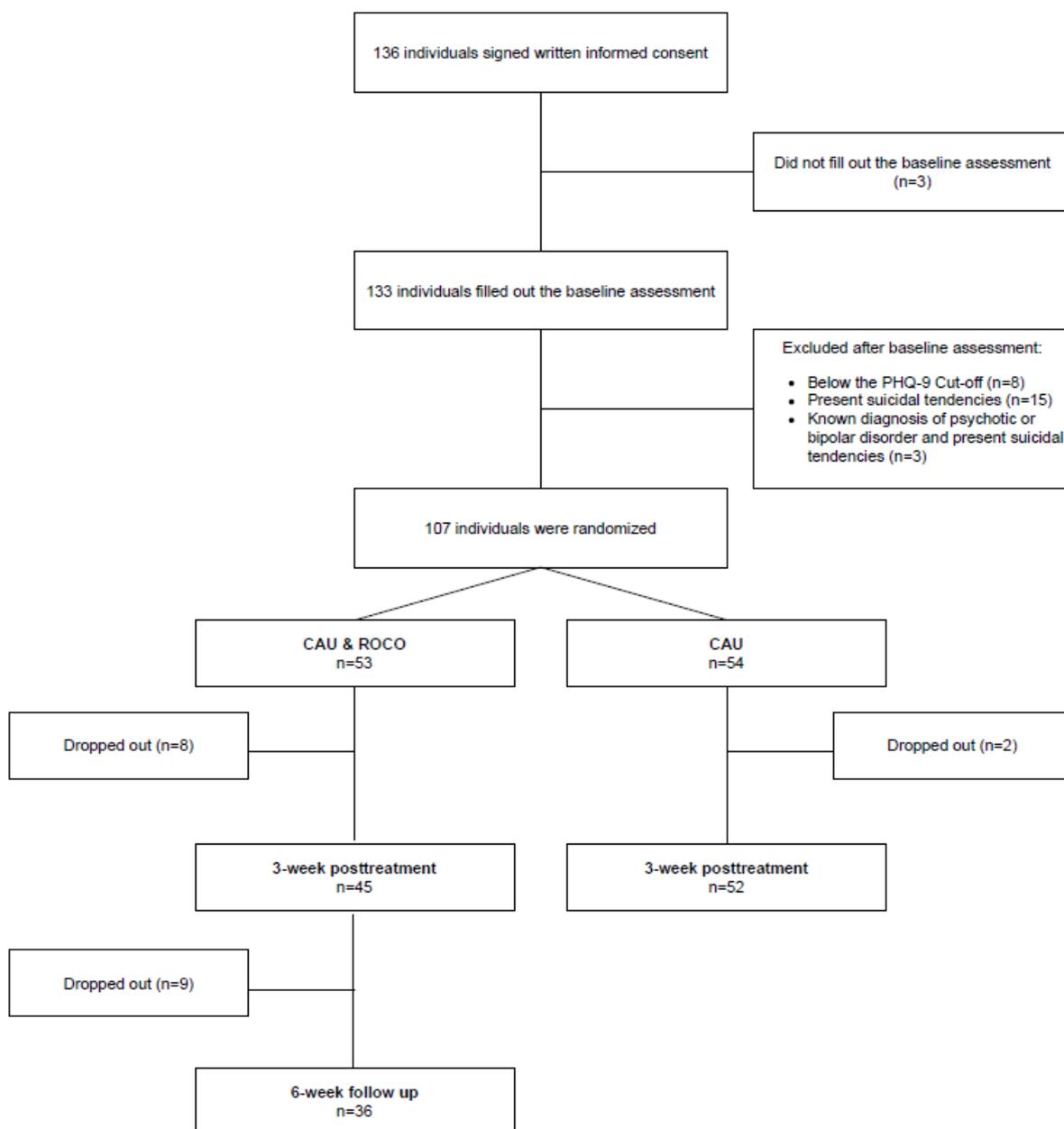
Participants were informed about their group allocation by e-mail. Participants allocated to the intermediate treatment group received an access code and registration instructions for the ROCO intervention. Three weeks after the start of the intervention the waiting period, all participants were asked to fill out an online post-assessment, consisting of the outcome measure questionnaires. After completing the post-assessment, participants in the waiting control group also were given access to the ROCO intervention. At 6 weeks after randomization, participants were asked to fill out the same outcome measure questionnaires again.

Measures

Primary outcome measure

All assessments were carried out online using self-report questionnaires. Participants filled out self-report questionnaires at pre-treatment, post-treatment (3 weeks) and follow-up (6 weeks after randomization). The primary outcome measure was the 9-item Patient Health Questionnaire (PHQ-9; Löwe et al., 2002), assessing the severity of depressive symptoms. The 9 items of the PHQ-9 correspond to the 9 DSM-IV criteria for depression. In the current sample, Cronbach's α was 0.71.

Secondary outcome measure

Secondary outcome measures include the Depression Anxiety Stress Scale (DASS-21; Lovibond & Lovibond, 1995) and the 12-Item Short-Form Health Survey (SF-12; Ware Jr et al., 1996). The DASS-21 assesses depressive mood, anxiety, and stress and is often used as measure of general psychological distress (Breedvelt et al., 2020). To address general psychological distress, we report the composite scale of the 21-item measure (Cronbach's α = 0.87). To assess quality of life the SF-12 was used. The 12-item measure consists of two subscales, a Physical Component Score and a Mental Component Score. The SF-12 is widely used and has a good test-retest reliability (Gandek et al., 1998).

Further secondary outcome measures are the 10-item Life Orientation Test Revised (LOT-R; Glaesmer et al., 2008), the 6-item version of the Bern Embitterment Inventory (BEI; Znoj & Schnyder, 2014), and the 10-item General Self-Efficacy Scale (GSE; Jerusalem & Schwarzer, 2003). The LOT-R assesses generalized optimism (Cronbach's α = 0.73) and pessimism (Cronbach's α = 0.77), while the BEI assesses embitterment, defined as the feeling of being disadvantaged by others and fate (Cronbach's α = 0.77), and the GSE assesses optimistic self-beliefs (Cronbach's α = 0.88).

Furthermore, emotion regulation skills were assessed using the 27-item Self-report Measure to measure emotion regulation skills (SEK-27; Berking & Znoj). For this study, the composite score is reported (Cronbach's α = 0.93). Moreover, loneliness and resilience were assessed using the 9-item version of the UCLA Loneliness Scale (ULS; Luhmann et al., 2016) and the 10-item version of the Connor-Davidson Resilience Scale (CD-RISC; Connor & Davidson, 2003), respectively. The internal consistencies in the current sample were Cronbach's α = 0.85 for the ULS and Cronbach's α = 0.85 for the CD-RISC.

In addition, overall satisfaction with and usability of the internet-based self-help intervention were assessed post-treatment using the Client Satisfaction Questionnaire-8 (CSQ-8; Attkisson & Zwick, 1982) and the System Usability Scale (SUS; Brooke, 1996), respectively.

Last, the 4-item SBQ-R (Osman et al., 2001), which has been used to screen for the presence of suicidal tendencies, was also used to assess possible worsening of suicidal tendencies during the use of the internet-based self-help intervention. However, the internal consistency of the SBQ-R was unacceptable in the current sample (Cronbach's α = 0.34), and results concerning the SBQ-R should be considered with caution.

Description of intervention

Participants in the intervention group received access to the internet-based self-help intervention ROCO (stands for resilience and optimism during COVID-19), specifically

addressing persons experiencing COVID-19 related psychological distress. ROCO is a 3-week self-help intervention consisting of 6 thematic modules. All modules contain brief texts, videos, illustrations, exercises, and a weekly task. The modules are based on cognitive behavioral therapy, focusing on *(a)* psychoeducation about COVID-19 related psychological distress, *(b)* emotion regulation skills, *(c)* identifying and restructuring thought patterns, *(d)* strengthening resilience, and *(e)* fostering relaxation and self-care. For a detailed description of the modules see Table 1.

Table 1.

Outline of the content of the internet-based self-help intervention ROCO

Introduction	Information on the self-help intervention and its handling
1. Identifying consequences and challenges	Psychoeducation on COVID-19 related psychological distress, evaluation of the current well-being (bodily sensations, positive, and negative feelings), resource-oriented weekly task
2. Understanding own feelings	Psychoeducation on emotions such as anxiety, helplessness, anger, sense of shame, and sadness, emotion regulation skills, acceptance-oriented weekly task
3. Changing the perspective	Psychoeducation on the influence of thoughts, automatic thoughts, rumination, and irrational beliefs, restructuring thought patterns, weekly task on rumination
4. Strengthening resilience	Psychoeducation on resilience, promoting coping, joie de vivre, and optimism, resource-oriented weekly task
5. Finding rest	Psychoeducation on sleep, sleep hygiene, and relaxation techniques, progressive muscle relaxation as weekly task
6. Taking care of oneself	Psychoeducation on the concept of post-traumatic growth and the importance of indulgence, gratitude and mindfulness exercises, resource-based weekly task
Conclusion	Information on maintaining and transferring what has been learned into everyday life

The modules are preceded by an introduction and rounded off by a conclusion. The self-help intervention also comprises information on what to do in an acute crisis, including a list of emergency contacts. Furthermore, an overview of the weekly tasks can be found, as well as a symptom-tracking questionnaire, allowing participants to track their self-reported symptoms.

Participants had access to all modules at all times. However, they were encouraged to work through two of the 6 modules per week. The individual modules require 40 to 80 minutes to complete. Since participants were able to access all self-help intervention content at any time ,they could thus determine the timing and order in which they worked through the self-help intervention. While working on the self-help intervention, participants had the possibility to enable reminders that encouraged them to log in to the self-help intervention again after a certain period of inactivity.

Furthermore, a guidance on demand approach was applied. Guidance on demand implies that support is only established when requested by a participant, but there is no scheduled contact per se. Therefore, participants could demand guidance via text-based chat function in the self-help intervention. They were informed that a psychologist would answer their request within 3 working days.

Statistical analysis

Analyses were conducted in SPSS according to an intention-to-treat principle. We conducted independent samples t tests and χ^2 tests (nominal data) to test group differences in demographic data and pre-treatment outcome measures. The efficacy of the intervention was tested with a mixed-model repeated-measures analysis of variance with time (pre-post) as a within-group factor and treatment as a between-group factor. Mixed models offer some advantages: First, in mixed models, all available data from each participant is used. Therefore, missing values are not substituted, but the parameters of the missing values are estimated.

Second, mixed models account for the dependence of data and correlation of repeated measures within individuals (Bell & Fairclough, 2014; Gueorguieva & Krystal, 2004).

We computed a separate model for each outcome measure. We used a compound symmetry covariance structure since it provided the best model fit based on Bayesian Information Criteria (BIC). We calculated Cohen's *d* for within- and between-group effect sizes based on estimated means and the pooled standard deviations of the observed means. In order to control for the baseline measures, we computed effect sizes sensu Morris (2008) for the pre-post comparison for the intervention group and the waiting control group. We calculated a Reliable Change Index (RCI; Jacobson & Truax, 1992) for depressive symptoms to analyze negative effects of the intervention (PHQ-9 = 4.69).To test the stability of the effects from post-treatment to the follow-up, within-group changes in outcome scores from post-assessment to follow-up assessment were analyzed using paired *t* tests. Only completers were included in the analysis of follow-up data. To compare drop-outs and completers we conducted independent *t* tests and χ^2 tests (nominal data).

Results

Baseline Evaluation

The mean age of the 107 German-speaking participants was 40.36 years (SD = 14.59, range = 18-81 years). The majority were female (*n* = 87, 81.3%), of Swiss origin (*n* = 78, 72.9%), single (*n* = 65, 60.7%) went to university (*n* = 64, 59.8%), and were engaged in full-time (*n* = 27, 25.2%) or part-time paid work (*n* = 51, 47.5%). In total, 28 participants (26.2%) were in concurrent psychological treatment and 24 participants (22.4%) were taking medication for psychological problems. A large percentage of the participants had previous experiences with psychological treatment (*n* =68, 63.6%). Based on the PHQ-9, the average depression score was 11.07 (SD = 4.23); 38.3% of the participants reported a mild, 39.3% a moderate, and 22.4% a severe depression. Participants initiated the participation in the study after they found the study website through a search on the internet (26.2%), after they read

about the study on social media (13.1%) or in newspaper articles (16.8%), saw flyers (6.5%), and as a response to recommendations from a health professional (13.1%) or other sources such as friends or university services (23.4%).

Table 2 presents the baseline characteristics of the participants and between-group comparisons. There was a significant between-group difference in terms of education. Persons in the treatment group were less educated ($\chi^2_{(2)} = 8.03$, $p = 0.02$, *Cramer's V* $= 0.27$). The groups did not differ significantly on any of the remaining demographic characteristics or other variables. Moreover, there were no significant between-group pre-treatment differences on any of the primary or secondary outcome measures (*p*'s > 0.08).

Table 2.

Demographics and sample characteristics at baseline for the treatment and waiting control group

	Total N = 107	Treatment group n = 53	Control group n = 54	Statistic
Age, *M* (SD)	40.36 (14.59)	40.68 (15.55)	40.04 (13.73)	$t_{(105)}$= 0.23, *p* =0.82[b]
Gender, *n* (%)				$\chi^2_{(1)}$ =1.60, *p* =0.21[a]
Male	19 (17.8)	7 (13.2)	12 (22.2)	
Female	87 (81.3)	46 (86.8)	41 (75.9)	
Non-binary	1 (0.9)	-	1 (1.9)	
Current marital status, *n* (%)				$\chi^2_{(1)}$ =0.24, *p* =0.63[a]
Single	65 (60.7)	36 (67.9)	29 (53.7)	
Married / Civil Union	30 (28.0)	15 (28.3)	15 (27.8)	
Divorced / Civil Union annulled	11 (1.3)	2 (3.8)	9 (16.7)	
Widowed / Civil partner died	1 (0.9)	-	1 (1.9)	
Education, *n* (%)				$\chi^2_{(2)}$ =8.03 *p* =0.02[a]
Compulsory School	3 (2.8)	2 (3.8)	1 (1.9)	
Apprenticeship	21 (19.6)	16 (30.2)	5 (9.3)	
Secondary II	19 (17.8)	9 (17.0)	10 (18.6)	
University	64 (59.8)	26 (49.0)	38 (70.4)	
Employment, *n* (%)				$\chi^2_{(3)}$ =0.86, *p* =0.84[a]
Full-time paid work	27 (25.2)	14 (26.4)	13 (24.1)	
Part-time paid work	51 (47.5)	24 (45.3)	27 (50.0)	
Unemployed	3 (2.8)	2 (3.8)	1 (1.9)	
At-home parent	4 (3.7)	3 (5.7)	1 (1.9)	
Student	13 (12.1)	5 (9.4)	8 (14.8)	
Retired	9 (8.4)	5 (9.4)	4 (7.4)	
Nationality, *n* (%)				$\chi^2_{(1)}$ =0.46, *p* =0.50[a]
Swiss	78 (72.9)	36 (67.9)	42 (77.8)	
German Speaking countries	26 (24.3)	14 (26.5)	12 (22.3)	
Other Countries	3 (2.7)	3 (5.7)	-	
Psychological Treatment, n (%)				
Past	68 (63.6)	38 (71.7)	30 (55.6)	$\chi^2_{(1)}$ =3.01, *p* =0.08
Current	28 (26.2)	14 (26.4)	14 (25.9)	$\chi^2_{(1)}$ =0.00, *p* =0.95
Current Medications, n (%)	24 (22.4)	14 (26.4%)	10 (18.5)	$\chi^2_{(1)}$ =0.96, *p* =0.33
Depressive symptoms				
Gesamtwert, M (SD)	11.07 (4.23)	11.13 (4.36)	11.00 (4.14)	$t_{(105)}$= 0.16, *p* =0.88[b]
Mild, n (%)	41 (38.3)	21 (39.6)	20 (37.0)	$\chi^2_{(2)}$ =1.54, *p* =0.46
Moderate, n (%)	42 (39.3)	18 (34.0)	24 (44.4)	
Severe, n (%)	24 (22.4)	14 (6.4)	10 (18.5)	

[a] Chi-Square calculations include only categories with a frequency > 3.

[b] Bootstrap 1000 samples.

Drop-out analysis and adherence to treatment

Of the 107 randomized participants, 97 (90.7%) completed the post-assessment, whereas 10 participants (9.3%) did not fill out the post-assessment (see Fig.1). There were no significant differences in terms of demographics and primary and secondary outcome measures at pre-treatment between participants who did and who did not fill out the post-assessment (p's > 0.08). However, participants who did not fill out the post-assessment spent significantly less time in the self-help intervention (M_{DO} = 47 min, SD_{DO} = 1 h 32 min vs. M_C = 4 h 18 min, SD_C = 3 h 58 min, $t_{(27.2)}$ = 4.39, p = 0.003, d = 0.95) and completed significantly less modules (M_{DO} = 2, SD_{DO} = 2.07 vs. M_C = 4.53, SD_C = 2.10, $t_{(9.7)}$ = 3.18, p = 0.004, d = 1.21). A module was considered as completed if there was a timestamp (time at which the module was accessed) for the corresponding module. Since each module consisted of only one page, a timestamp indicated that the module had been consulted. Among participants who completed at least one module (48 of 53 participants in the intervention group), drop-out was 12.5%. Moreover, there was a tendency that participants who did not fill out the post-assessment were more often in the intervention group (15.1% vs. 3.7%).

Out of the 53 participants in the intervention group, 36 completed the follow-up questionnaires (67.9%). Drop-out at follow-up was associated with significantly lower usability ratings of the self-help intervention (M_{DO} = 66.25, SD_{DO} =11.91 vs. M_C = 87.5, SD_C = 11.91, $t_{(6.8)}$ = 4.038, p = 0.005, d = 1.8) and fewer completed modules (M_{DO} = 2.17, SD_{DO} = 2.2 vs. M_C = 5.11, SD_C = 1.66, $t_{(6)}$ = 3.1, p = 0.021, d = 1.6).

On average, participants completed four of the six modules (M = 4.15, SD = 2.27, range = 0-6 modules) and 54.7% of participants completed all modules. Five participants did not log in to the self-help intervention (9.4%). The mean time spent in the self-help intervention was 3 hours and 47 minutes (SD = 3 h 54 min, range: 0 min – 22 h 24 min). Only three participants demanded guidance via text-based chat function and 15 messages were exchanged in total. Pre-post changes of the outcome measures did not correlate with the

number of completed modules nor with usage time, with one exception: The pre-post changes

in loneliness, assessed by the ULS, correlated significantly with the number of completed

modules ($r_s = 0.395$, $p = 0.009$), meaning that the more modules were completed the higher

the reduction in loneliness tended to be.

Table 3

Observed and estimated means for primary and secondary outcome measures and within- and between-group effect sizes

Outcome	Pre-treatment	n	Post-treatment (observed)	n	Post-treatment (estimated)	n	Follow up (observed)	n	Post-treatment between group comparisons[a]	Pre-Post within group effect sizes (estimated means)	Between-group effect sizes at post-treatment (estimated means)
	M (SD)		M (SD)		M (SE)		M (SD)		$F_{(df)}$, p	d_{Cohen} (95% CI)	d_{ppc2} sensu morris
PHQ-9											
Intervention	11.13 (4.36)	53	9.56 (3.70)	45	9.63 (0.59)	53	8.75 (5.07)	36	$F_{(1,97.6)} = 0.048$,	0.37 (-0.18-0.91)	0.04
Control	11.00 (4.14)	54	9.60 (3.89)	52	9.67 (0.56)	54			$p = 0.827$	0.33 (-0.21-0.87)	
DASS-21											
Intervention	21.53 (9.23)	53	20.27 (10.84)	45	20.66 (1.39)	53	17 (10.44)	36	$F_{(1,97.0)} = 1.732$,	0.09 (-0.45-0.63)	-0.19
Control	22.37 (9.86)	54	19.33 (9.13)	52	19.66 (1.34)	54			$p = 0.191$	0.29 (-0.25-0.82)	
SF-12 MH											
Intervention	31.10 (9.10)	53	36.72 (11.01)	43	36.47 (1.35)	53	38.31 (10.40)	36	$F_{(1,98.3)} = 1.586$,	0.54 (-0.01-1.09)	0.24
Control	28.81 (7.73)	54	32.23 (9.20)	52	32.14 (1.27)	54			$p = 0.211$	0.39 (-0.15-0.93)	
SF-12 PH											
Intervention	53.43 (8.79)	53	50.96 (10.03)	43	51.26 (1.16)	53	51.26 (11.24)	36	$F_{(1,96.3)} = 0.005$,	-0.23 (-0.77-0.31)	0.01
Control	56.11 (6.98)	54	53.87 (6.43)	52	53.86 (1.10)	54			$p = 0.942$	-0.34 (-0.87-0.20)	
LOT-R O											
Intervention	7.19 (2.73)	53	7.52 (2.62)	42	7.45 (0.38)	53	7.69 (2.86)	36	$F_{(1,92.1)} = 0.674$	0.10 (-0.44-0.64)	0.12
Control	6.87 (2.33)	54	6.84 (2.65)	50	6.82 (0.36)	54			$p = 0.414$	-0.02 (-0.55-0.51)	
LOT-R P											
Intervention	4.75 (2.76)	53	4.67 (2.39)	42	4.63 (0.39)	53	4.58 (2.31)	36	$F_{(1,92.2)} = 0.027$,	0.05 (-0.49-0.59)	-0.02
Control	4.70 (2.63)	54	4.62 (2.91)	50	4.64 (0.37)	54			$p = 0.969$	0.02 (-0.51-0.56)	

	M (SD)	n	M (SD)	n	M (SE)	n	M (SD)	n			
BEI											
Intervention	8.75 (4.88)	53	8.45 (4.23)	42	8.52 (0.71)	53	7.61 (4.69)	36	$F_{(1,93.1)} = 0.075$,	0.05 (-0.49-0.59)	0.04
Control	10.07 (4.96)	54	9.50 (5.22)	50	9.62 (0.68)	54			$p = 0.785$	0.09 (-0.45-0.62)	
ULS											
Intervention	21.26 (4.82)	53	19.88 (4.56)	43	20.12 (0.64)	53	19.28 (4.94)	36	$F_{(1,95.3)} = 2.155$	0.24 (-0.30-0.78)	0.20
Control	20.37 (4.25)	54	20.27 (4.04)	52	20.16 (0.61)	54			$p = 0.145$	0.05 (-0.48-0.58)	
GSE											
Intervention	25.91 (4.47)	53	26.88 (4.81)	43	26.88 (0.66)	53	27.03 (5.35)	36	$F_{(1,95.5)} = 1.405$	0.21 (-0.33-0.75)	0.17
Control	26.56 (4.72)	54	26.69 (4.47)	51	26.74 (0.63)	54			$p = 0.239$	0.04 (-0.49-0.57)	
SEK-27											
Intervention	62.64 (15.45)	53	73.33 (15.19)	42	71.68 (2.33)	53	73.92 (17.57)	36	$F_{(1,93.6)} = 5.661$	0.59 (0.04-1.14)	0.35
Control	59.83 (16.61)	54	62.76 (16.65)	50	63.17 (2.22)	54			$p = 0.019$	0.20 (-0.33-0.74)	
CD-RISC											
Intervention	21.87 (6.62)	53	23.48 (6.43)	42	23.47 (0.92)	53	23.11 (6.51)	36	$F_{(1,92.8)} = 6.523$	0.25 (-0.30-0.79)	0.38
Control	23.78 (5.47)	54	23.10 (6.75)	50	23.05 (0.88)	54			$p = 0.012$	-0.12 (-0.65-0.42)	
SBQ-R											
Intervention	4.92 (1.36)	53	5.18 (1.78)	45	5.15 (0.21)	53	5.36 (1.79)	36	$F_{(1,97.3)} = 0.010$,	-0.15 (-0.69-0.39)	-0.02
Control	4.72 (1.28)	54	4.92 (1.41)	52	4.93 (0.20)	54			$p = 0.919$	-0.16 (-0.69-0.38)	

Note. M, mean; SD, standard deviation; SE, standard error; df, degrees of freedom; CI, confidence interval; PHQ-9, Patient Health Questionnaire; DASS-21, Depression Anxiety Stress Scale; SF-12 MH, Short-Form Health Survey mental health subscale, SF-12 PH, Short-Form Health Survey physical health subscale; LOT-R O, Life Orientation Test Revised optimism subscale; LOT-R P, Life Orientation Test Revised pessimism subscale; BEI, Bern Embitterment Inventory; ULS, UCLA Loneliness Scale; GSE, General Self-Efficacy Scale; SEK-27, Self-report Measure to measure emotion regulation skills; CD-RISC, Connor-Davidson Resilience Scale; SBQ-R, Suicide Behavior Questionnaire Revised.

[a] Intention-to-treat analysis.

Overall effects at post-treatment

The observed and estimated means for the primary and secondary outcome measures are displayed in Table 3. For each outcome measure, a linear mixed model with group as a fixed factor and time as a repeated factor was calculated (see Table 3).

The primary outcome measure, the PHQ-9, was not qualified by a significant group x time interaction ($F_{(1,97.6)} = 0.048$, $p = 0.827$). Between-group effect size controlling for pre-measurement sensu Morris (2008) for depressive symptoms was $d = 0.04$. Likewise, the mixed-model analyses revealed no significant group x time interactions for the following secondary outcome measures: DASS-21, mental and physical health subscales of the SF-12, optimism and pessimism subscales of the LOT-R, BEI, ULS, and GSE (all F's (degrees of freedom 1, 92.1-98.3) < 2.155, all p's > 0.145). Between-group effect sizes controlling for pre-measurement sensu Morris (2008) ranged between $d = 0.01 - 0.24$ (absolute values).

The SEK-27 as measure of emotion regulation skills and CD-RISC as measure of resilience were qualified by significant group x time interactions (CD-RISC*: $F_{(1,92.8)} = 6.523$, $p = 0.012$; SEK-27: $F_{(1,93.6)} = 5.661$, $p = 0.019$). Between-group effect sizes controlling for pre-measurement sensu Morris (2008) were small-to-medium with $d = 0.35$ (SEK-27) and $d = 0.38$ (CD-RISC). Within-group comparisons in the intervention group revealed small and medium effect sizes (CD-RISC: $d = 0.25$; SEK-27: $d = 0.59$). Within-group effect sizes in the waiting control group were $d = -0.12$ for the CD-RISC, respectively $d = 0.20$ for the SEK-27.

To explore whether concurrent psychological treatment or medication intake during the self-help intervention moderated pre-post effects on outcome measures, we included the corresponding variables in the mixed-model analyses and tested the significance of the three-way interaction between time, group, and concurrent psychological treatment or medication intake. None of the three-way interactions were significant (all p's > 0.054) with two exceptions: both three-way interactions for the DASS-21 were significant (psychological treatment: $F_{(1,95.06)} = 4.626$, $p = 0.034$; medication intake: $F_{(1,92.40)} = 4.526$, $p = 0.036$). For

both, concurrent psychological treatment and medication intake, only time x group interactions among participants receiving concurrent psychological treatment / medication became significant (psychological treatment: $F_{(1,23.4)} = 6.14$, $p = 0.021$ vs. $F_{(1,71.45)} = 0.002$, $p = 0.962$; medication intake: $F_{(1,19.5)} = 4.647$, $p = 0.044$ vs. $F_{(1,72.8)} = 0.037$, $p = 0.848$). Between-group effect sizes controlling for pre-measurement sensu Morris (2008) were higher among those participants receiving psychological treatment or medication [psychological treatment: $d = -0.73$ vs. $d = 0.01$; medication intake: $d = -0.85$ vs. $d = 0.05$]. Participants who received both the internet-based self-help intervention and concurrent psychological treatment or medication showed worsening on the DASS-21 (see Table 4 for observed and estimated means).

Table 4

Observed and estimated means for the DASS-21 and within- and between-group effect sizes, considering concurrent psychological treatment and

medication intake

Outcome	Pre-treatment	n	Post-treatment (observed)	n	Post-treatment (estimated)	n	Post-treatment between group comparisons[a]	Pre-Post within group effect sizes (estimated means)	Between-group effect sizes at post-treatment (estimated means)
	M (SD)		M (SD)		M (SE)		$F_{(df)}$, p	d_{Cohen} (95% CI)	d_{ppc2} sensu morris
DASS-21									
Concurrent psychological treatment									
Intervention	22.86 (8.51)	14	25.00 (10.58)	12	25.77 (2.69)	14	$F_{(1,23.4)} = 6.14$,	-0.31 (-1.36-0.75)	-0.73
Control	21.07 (9.68)	14	16.54 (8.59)	13	17.17 (2.64)	14	$p = 0.021$	0.43 (-0.63-1.49)	
No concurrent psychological treatment									
Intervention	21.05 (9.53)	39	18.66 (10.56)	33	18.81 (1.62)	39	$F_{(1,71.45)} = 0.002$,	0.22 (-0.41-0.85)	0.01
Control	22.83 (10.00)	40	20.26 (9.22)	39	20.51 (1.54)	40	$p = 0.962$	0.24 (-0.38-0.86)	
DASS-21									
Concurrent medication intake									
Intervention	25.29 (7.62)	14	27.91 (12.01)	11	27.53 (2.63)	14	$F_{(1,19.5)} = 4.647$,	-0.23 (-1.28-0.82)	-0.85
Control	31.20 (9.86)	10	25.90 (11.61)	10	25.90 (2.93)	10	$p = 0.044$	0.49 (-0.77-1.75)	
No concurrent medication intake									
Intervention	20.18 (9.59)	38	17.82 (9.48)	33	18.37 (1.56)	38	$F_{(1,72.8)} = 0.037$	0.19 (-0.45-0.83)	0.05
Control	20.51 (8.83)	43	17.93 (7.83)	41	18.40 (1.43)	43	$p = 0.848$	0.25 (-0.35-0.85	

Note. M, mean; SD, standard deviation; SE, standard error; df, degrees of freedom; CI, confidence interval; DASS-21, Depression Anxiety Stress Scale.

[a] Intention-to-treat analysis.

Treatment satisfaction

Overall, participants were satisfied with the self-help intervention. The mean score on the CSQ-8 was 3.09 (SD =0.61), corresponding to mostly satisfied (3). In addition, participants were very satisfied with the usability of the self-help intervention. The mean score on the SUS was 84.39 (SD = 14.01), lying between good (71.4) and excellent (85.5; Bangor et al., 2009).

Suicidal tendencies and negative effects

A linear mixed model with group as fixed factor and time as repeated factor (pre-post) was conducted for the worsening of suicidal tendencies. There was no significant group x time interaction on the SBQ-R ($F_{(1,97.3)} = 0.010$, $p = 0.919$). Observed and estimated means for the SBQ-R are presented in Table 3. Regarding negative effects, the RCI showed that in the intervention group, 20% of the participants deteriorated on depressive symptoms and in the waiting control group, 19.23% of the participants deteriorated on depressive symptoms.

3.6. Stability of effects

Observed means and standard deviations at the 6-week follow-up for the primary and secondary outcome measures are displayed in Table 3. Only participants in the intervention group who completed all three assessments (pre, post, and follow-up) were included. DASS-21 scores decreased significantly from post-treatment to follow-up ($t_{(35)} = 2.314$, $p = 0.027$, $d_z = 0.38$). There were no significant post-treatment to follow-up changes in the primary and the other secondary outcome measures ($t_{(35)}$'s = 0.170-1.617, p's = 0.115-0.866).

Discussion

In this trial, the efficacy of an internet-based self-help intervention for COVID-19 related psychological distress – ROCO – was investigated. The results show that the 3-week internet-based self-help intervention was not effective in reducing depressive, anxiety, and stress

symptoms. There could be several reasons for this result: First, participants in this trial showed on average moderate depressive symptoms (primary outcome) at baseline. Meta-analyses indicate that the severity of depressive symptoms at baseline influence treatment effects (Bower et al., 2013; Fournier et al., 2010). For example, in their meta-analysis of low-threshold internet-based interventions, Bower et al. (2013) found that participants who are initially more severely depressed show larger treatment effects compared to participants with lower initial symptom severity. Similar results were reported by Fournier et al. (2010) in their meta-analysis on antidepressant medication and depression severity. The benefit of antidepressant medication increased with the severity of depressive symptoms. Such results can be explained by the fact that more severe depressive symptoms offer more room for improvement than mild or moderate depressive symptoms. Second, the ROCO intervention is rather short, with a duration of three weeks. Although internet-based interventions often are shorter compared to face-to-face therapies (van Beugen et al., 2014), it is possible that the ROCO intervention was too short to produce more and stronger changes for example in depressive symptoms. A study by Christensen et al. (2006) suggests that longer internet-based interventions are more effective in reducing depressive symptoms than shorter ones. However, heavy time constraints are one of the most common reasons for high attrition in internet-based interventions (Christensen et al., 2006; Christensen et al., 2009), which in turn would be an argument for shorter interventions. Third, we used the PHQ-9 to assess depressive symptoms. Although short measurement instruments such as the PHQ-9 are widely used, they also carry some risks (Titov & Andersson, 2021). Regarding the PHQ-9, for example, significantly more cases of major depression are detected when using simple cut-off scores than when using additional criteria consistent with DSM-IV (Titov & Andersson, 2021). Therefore, the use of convenient cut-off scores for the PHQ-9 could

lead to over-identification of individuals with clinically relevant depressive symptoms. Accordingly, our sample may have included individuals for whom psychological treatment would not be necessary and who, accordingly, would not benefit from such treatment (Titov & Andersson, 2021). Fourth, while several studies suggest that the COVID-19 pandemic has a lasting negative impact on mental health (Daly et al., 2020; Kikuchi et al., 2020), a study from the U.S. reports an initial increase in psychological distress at the onset of the COVID-19 pandemic that was followed by a decline in psychological distress in the months thereafter (Daly & Robinson, 2021). Such findings may indicate that although there was a substantial increase in psychological distress at the onset of the COVID-19 pandemic, there may be a decrease in psychological distress over time. A trajectory like this, which is characterized by a decline in mental health at the time of an adversity followed by a gradual improvement coming close to previous levels, is referred to as recovery in resilience research (Infurna & Luthar, 2018). Recovery is a common response to other major life stressors or potentially traumatic events (Clark & Georgellis, 2013; Galatzer-Levy et al., 2018). In accordance with this assumption of recovery, both groups in this trial show improvements in the primary outcome, depressive symptoms, over time. Within-group effect sizes are small-to-medium (intervention group, $d = 0.37$, waiting control group $d = 0.33$). Therefore, it is questionable whether an early intervention to reduce psychological distress is necessary at all or if it is advisable to first observe if recovery occurs. However, since other studies have found that internet-based self-help interventions are effective in reducing COVID-19 related depressive symptoms (Al-Alawi et al., 2021; Aminoff et al., 2021; Wahlund et al., 2021), more research is needed to identify under which circumstances internet-based self-help interventions are effective in reducing COVID-19 related depressive symptoms and for whom. Nonetheless, the ROCO intervention led to an increase in emotion

regulation (between-group effect of d =0.35) and resilience (between-group effect of d =0.38) as early as 3 weeks after treatment initiation. The effects remained stable in the 6-week follow-up. Given the content of the ROCO intervention, the improvement in emotion regulation and resilience is plausible. ROCO includes both a module that addresses emotions and emotion regulation and a module that focuses on strengthening resilience. Accordingly, the results could be explained by the content of the ROCO intervention. Taking into account that increasing resilience was mentioned as a consideration for dealing with the COVID-19 pandemic, these are encouraging results (Habersaat et al., 2020). Moreover, it has been shown that deficits in emotion regulation skills are associated with psychopathology such as depressive symptoms (Silk et al., 2003; Williams et al., 2004), while successful emotion regulation facilitates emotional adjustment (Berking et al., 2008). In the case of ROCO, these findings could indicate that the intervention only proves effective in the long-term, in particular when a new stressor occurs. Accordingly, the intervention could be particularly useful as first-step measure for preventive treatment.

Negative effect sizes for depressive, anxiety, and stress symptoms as measured by the DASS-21 were found for participants who were concurrently receiving psychological treatment (d =-0.73) or taking medication (d = -0.85). Even though the sample size for the three-way-interaction between time, group, and concurrent psychological treatment was small, these results might suggest that ROCO could be particularly beneficial for people who do not seek concurrent treatment. Lastly, the intervention group showed similar rates of deterioration with respect to depressive symptoms as the waiting control group. This result contradicts meta-analyses that showed that deterioration rates are lower in internet-based self-help interventions compared to control groups (Ebert et al., 2016; Karyotaki et al., 2018). One possible explanation for the

similar deteriorations in the two groups is that the COVID-19 pandemic is an ongoing stressor (Kira et al., 2021) and, that the ROCO intervention was not successful in halting the deterioration in depressive symptoms due to the COVID-19 pandemic.

Limitations

Several limitations of our study have to be considered. Participants in the waiting control group received access to the ROCO intervention after completing the post-assessment at the end of the three-week waiting period. For this reason, between-group comparisons are not possible for follow-up measurements, which is why we could only examine the stability of the effects for the intervention group and, moreover, cannot determine, whether the decrease of DASS-21 values from the post to the follow-up measurement was due to the intervention, recovery, or other reasons. Another limitation concerns randomization. The randomization was not ideal, since the analysis of the demographic data revealed a significant group difference regarding educational status. Moreover, although we assessed whether participants used other treatments or took medications in addition to the ROCO intervention at each measurement time point, we do not have information regarding the quantity and quality of those other treatments. Other treatments or medication might also influence the results and limit the generalizability of the study results. In this regard, the self-selection of the participants must be mentioned as another limitation. Due to self-selection, the participants may differ from the general population and the study results may be limited. Furthermore, we did not conduct a diagnostic interview, but used self-assessment questionnaires exclusively. Thus, we were not able to make diagnoses and the results may be affected by the subjective responses. Finally, drop-out rates at follow-up have to be mentioned as a limitation, even though drop-out rates at post-assessment were low.

Conclusions

Despite these limitations, the current trial provides further information on the use of internet-based self-help interventions during the COVID-19 pandemic. The investigated internet-based self-help intervention, ROCO, was not able to reduce primary depressive symptoms and is accordingly not suitable for the treatment of depressive symptoms. However, the present study showed evidence that the intervention has beneficial effects on emotion-regulation and resilience. These results suggest that the intervention may be useful for preventive purposes, such as dealing with potential future stressors. Future research is needed to examine for whom and how such an intervention is effective.

Conflicts of interest

No conflicts of interest to disclose.

Declarations

Ethical approval has been obtained by the Cantonal Ethics committee Bern (BASEC2020-00990). Informed consent was obtained from all participants in the study.

References

Al-Alawi, M., McCall, R. K., Sultan, A., Al Balushi, N., Al-Mahrouqi, T., Al Ghailani, A., . . . Al Sinawi, H. (2021). Efficacy of a six-week-long therapist-guided online therapy versus self-help internet-based therapy for COVID-19–induced anxiety and depression: open-label, pragmatic, randomized controlled trial. JMIR mental health, 8(2), e26683.

Aminoff, V., Sellén, M., Sörliden, E., Ludvigsson, M., Berg, M., & Andersson, G. (2021). Internet-Based Cognitive Behavioral Therapy for Psychological Distress Associated With the COVID-19 Pandemic: A Pilot Randomized Controlled Trial. Frontiers in Psychology, 12, 1998.

Andersson, G., & Titov, N. (2014). Advantages and limitations of Internet-based interventions for common mental disorders. World Psychiatry, 13(1), 4-11.

Attkisson, C. C., & Zwick, R. (1982). The Client Satisfaction Questionnaire: Psychometric properties and correlations with service utilization and psychotherapy outcome. Evaluation and program planning, 5(3), 233-237.

Bangor, A., Kortum, P., & Miller, J. (2009). Determining what individual SUS scores mean: Adding an adjective rating scale. Journal of usability studies, 4(3), 114-123.

Bell, M. L., & Fairclough, D. L. (2014). Practical and statistical issues in missing data for longitudinal patient-reported outcomes. Statistical methods in medical research, 23(5), 440-459.

Berking, M., Orth, U., Wupperman, P., Meier, L. L., & Caspar, F. (2008). Prospective effects of emotion-regulation skills on emotional adjustment. Journal of Counseling Psychology, 55(4), 485.

Berking, M., & Znoj, H. SEK-27. Fragebogen zur standardisierten Selbsteinschätzung

    emotionaler Kompetenzen [Verfahrensdokumentation aus PSYNDEX Tests-Nr.

    9005957, Fragebogen und Auswertungsanweisung]. (2011 ed.). In Leibniz-Zentrum für

    Psychologische Information und Dokumentation (ZPID). https://doi.org/

    https://doi.org/10.23668/psycharchives.387

Beutel, M. E., Klein, E. M., Brähler, E., Reiner, I., Jünger, C., Michal, M., . . . Lackner, K. J.

    (2017). Loneliness in the general population: prevalence, determinants and relations to

    mental health. BMC psychiatry, 17(1), 1-7.

Bower, P., Kontopantelis, E., Sutton, A., Kendrick, T., Richards, D. A., Gilbody, S., . . .

    Christensen, H. (2013). Influence of initial severity of depression on effectiveness of low

    intensity interventions: meta-analysis of individual patient data. Bmj, 346.

Breedvelt, J. J., Zamperoni, V., South, E., Uphoff, E. P., Gilbody, S., Bockting, C. L., . . .

    Kousoulis, A. A. (2020). A systematic review of mental health measurement scales for

    evaluating the effects of mental health prevention interventions. European journal of

    public health.

Brog, N. A., Hegy, J. K., Berger, T., & Znoj, H. (2021). An internet-based self-help intervention

    for people with psychological distress due to COVID-19: study protocol for a randomized

    controlled trial. Trials, 22(1), 171. https://doi.org/10.1186/s13063-021-05089-9

Brooke, J. (1996). SUS: a "quick and dirty'usability. Usability evaluation in industry, 189.

Christensen, H., Griffiths, K., Mackinnon, A., & Brittliffe, K. (2006). Online randomized

    controlled trial of brief and full cognitive behaviour therapy for depression. Psychological

    medicine, 36(12), 1737-1746.

Christensen, H., Griffiths, K. M., & Farrer, L. (2009). Adherence in internet interventions for

    anxiety and depression: systematic review. Journal of medical Internet research, 11(2),

    e1194.

Clark, A. E., & Georgellis, Y. (2013). Back to baseline in Britain: adaptation in the British

    household panel survey. Economica, 80(319), 496-512.

Connor, K. M., & Davidson, J. R. (2003). Development of a new resilience scale: The Connor-

    Davidson resilience scale (CD-RISC). Depression and anxiety, 18(2), 76-82.

Cuijpers, P., Donker, T., Johansson, R., Mohr, D. C., van Straten, A., & Andersson, G. (2011).

    Self-guided psychological treatment for depressive symptoms: a meta-analysis. PloS one,

    6(6), e21274.

Dallal, G. E. (2007, August 3). Randomization.com. Retrieved 10/07/2020 from

    http://www.randomization.com.

Daly, M., & Robinson, E. (2021). Psychological distress and adaptation to the COVID-19 crisis

    in the United States. Journal of psychiatric research, 136, 603-609.

Daly, M., Sutin, A. R., & Robinson, E. (2020). Longitudinal changes in mental health and the

    COVID-19 pandemic: Evidence from the UK Household Longitudinal Study.

    Psychological medicine, 1-10.

de Quervain, D., Aerni, A., Amini, E., Bentz, D., Coynel, D., Gerhards, C., . . . Schicktanz, N.

    (2020). The Swiss Corona Stress Study.

Donker, T., van Straten, A., Riper, H., Marks, I., Andersson, G., & Cuijpers, P. (2009).

    Implementation of Internet-based preventive interventions for depression and anxiety:

    role of support? The design of a randomized controlled trial. Trials, 10(1), 59.

    https://doi.org/10.1186/1745-6215-10-59

Dozois, D. J. (2020). Anxiety and depression in Canada during the COVID-19 pandemic: A national survey. Canadian Psychology/Psychologie canadienne.

Ebert, D., Donkin, L., Andersson, G., Andrews, G., Berger, T., Carlbring, P., . . . Johansson, R. (2016). Does Internet-based guided-self-help for depression cause harm? An individual participant data meta-analysis on deterioration rates and its moderators in randomized controlled trials. Psychological medicine, 46(13), 2679-2693.

Ettman, C. K., Abdalla, S. M., Cohen, G. H., Sampson, L., Vivier, P. M., & Galea, S. (2020). Prevalence of depression symptoms in US adults before and during the COVID-19 pandemic. JAMA network open, 3(9), e2019686-e2019686.

Fournier, J. C., DeRubeis, R. J., Hollon, S. D., Dimidjian, S., Amsterdam, J. D., Shelton, R. C., & Fawcett, J. (2010). Antidepressant drug effects and depression severity: a patient-level meta-analysis. Jama, 303(1), 47-53.

Galatzer-Levy, I. R., Huang, S. H., & Bonanno, G. A. (2018). Trajectories of resilience and dysfunction following potential trauma: A review and statistical evaluation. Clinical Psychology Review, 63, 41-55.

Gandek, B., Ware, J. E., Aaronson, N. K., Apolone, G., Bjorner, J. B., Brazier, J. E., . . . Prieto, L. (1998). Cross-validation of item selection and scoring for the SF-12 Health Survey in nine countries: results from the IQOLA Project. Journal of clinical epidemiology, 51(11), 1171-1178.

Glaesmer, H., Hoyer, J., Klotsche, J., & Herzberg, P. Y. (2008). Die deutsche version des Life-Orientation-Tests (LOT-R) zum dispositionellen Optimismus und Pessimismus. Zeitschrift für Gesundheitspsychologie, 16(1), 26-31.

Gueorguieva, R., & Krystal, J. H. (2004). Move over anova: progress in analyzing repeated-measures data andits reflection in papers published in the archives of general psychiatry. Archives of general psychiatry, 61(3), 310-317.

Habersaat, K. B., Betsch, C., Danchin, M., Sunstein, C. R., Böhm, R., Falk, A., . . . Sah, S. (2020). Ten considerations for effectively managing the COVID-19 transition. Nature human behaviour, 4(7), 677-687.

Halder, S. (2020). COVID-19: Psychological Impact and Psychotherapeutic Intervention. EC Psychology and Psychiatry, 9, 32-35.

Infurna, F. J., & Luthar, S. S. (2018). Re-evaluating the notion that resilience is commonplace: A review and distillation of directions for future research, practice, and policy. Clinical Psychology Review, 65, 43-56.

Jacobson, N. S., & Truax, P. (1992). Clinical significance: a statistical approach to defining meaningful change in psychotherapy research.

Jerusalem, M., & Schwarzer, R. (2003). SWE-Skala zur Allgemeinen Selbstwirksamkeitserwartung.

Karyotaki, E., Kemmeren, L., Riper, H., Twisk, J., Hoogendoorn, A., Kleiboer, A., . . . Botella, C. (2018). Is self-guided internet-based cognitive behavioural therapy (iCBT) harmful? An individual participant data meta-analysis. Psychological medicine, 48(15), 2456-2466.

Kikuchi, H., Machida, M., Nakamura, I., Saito, R., Odagiri, Y., Kojima, T., . . . Inoue, S. (2020). Changes in psychological distress during the COVID-19 pandemic in Japan: a longitudinal study. Journal of Epidemiology, 30(11), 522-528.

Kira, I. A., Shuwiekh, H. A., Ashby, J. S., Elwakeel, S. A., Alhuwailah, A., Sous, M. S. F., . . . Jamil, H. J. (2021). The impact of COVID-19 traumatic stressors on mental health: Is COVID-19 a new trauma type. International journal of mental health and addiction, 1-20.

Liu, K., Chen, Y., Wu, D., Lin, R., Wang, Z., & Pan, L. (2020). Effects of progressive muscle relaxation on anxiety and sleep quality in patients with COVID-19. Complementary Therapies in Clinical Practice, 101132.

Lovibond, P. F., & Lovibond, S. H. (1995). The structure of negative emotional states: Comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. Behaviour research and therapy, 33(3), 335-343.

Löwe, B., Spitzer, R. L., Zipfel, S., & Herzog, W. (2002). Komplettversion und Kurzform. In: Pfizer.

Luhmann, M., Bohn, J., Holtmann, J., Koch, T., & Eid, M. (2016). I'm lonely, can't you tell? Convergent validity of self-and informant ratings of loneliness. Journal of Research in Personality, 61, 50-60.

Luo, M., Guo, L., Yu, M., & Wang, H. (2020). The Psychological and Mental Impact of Coronavirus Disease 2019 (COVID-19) on Medical Staff and General Public–A Systematic Review and Meta-analysis. Psychiatry Research, 113190.

Morris, S. B. (2008). Estimating effect sizes from pretest-posttest-control group designs. Organizational research methods, 11(2), 364-386.

Osman, A., Bagge, C. L., Gutierrez, P. M., Konick, L. C., Kopper, B. A., & Barrios, F. X. (2001). The Suicidal Behaviors Questionnaire-Revised (SBQ-R): validation with clinical and nonclinical samples. Assessment, 8(4), 443-454.

Rajkumar, R. P. (2020). COVID-19 and mental health: A review of the existing literature. Asian journal of psychiatry, 102066.

Silk, J. S., Steinberg, L., & Morris, A. S. (2003). Adolescents' emotion regulation in daily life: Links to depressive symptoms and problem behavior. Child development, 74(6), 1869-1880.

Soklaridis, S., Lin, E., Lalani, Y., Rodak, T., & Sockalingam, S. (2020). Mental health interventions and supports during COVID-19 and other medical pandemics: A rapid systematic review of the evidence. General hospital psychiatry, 66, 133-146.

Sotoudeh, H. G., Alavi, S. S., Akbari, Z., Jannatifard, F., & Artounian, V. (2020). The effect of brief crisis intervention package on improving quality of life and mental health in patients with COVID-19. Iranian journal of psychiatry, 15(3), 205.

Titov, N., & Andersson, G. (2021). Using brief measures to identify depression and other mental disorders: a challenge for research and clinical practice. Internet interventions, 100450.

van Beugen, S., Ferwerda, M., Hoeve, D., Rovers, M. M., Spillekom-van Koulil, S., van Middendorp, H., & Evers, A. W. (2014). Internet-based cognitive behavioral therapy for patients with chronic somatic conditions: a meta-analytic review. Journal of medical Internet research, 16(3), e88.

Wahlund, T., Mataix-Cols, D., Lauri, K. O., de Schipper, E., Ljótsson, B., Aspvall, K., & Andersson, E. (2021). Brief online cognitive behavioural intervention for dysfunctional worry related to the COVID-19 pandemic: a randomised controlled trial. Psychotherapy and Psychosomatics, 90(3), 191-199.

Wang, C., Pan, R., Wan, X., Tan, Y., Xu, L., Ho, C. S., & Ho, R. C. (2020). Immediate psychological responses and associated factors during the initial stage of the 2019

coronavirus disease (COVID-19) epidemic among the general population in China. International journal of environmental research and public health, 17(5), 1729.

Ware Jr, J. E., Kosinski, M., & Keller, S. D. (1996). A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Medical care, 220-233.

Wei, N., Huang, B.-c., Lu, S.-j., Hu, J.-b., Zhou, X.-y., Hu, C.-c., . . . Wang, Z. (2020). Efficacy of internet-based integrated intervention on depression and anxiety symptoms in patients with COVID-19. Journal of Zhejiang University. Science. B, 1.

Wiersinga, W. J., Rhodes, A., Cheng, A. C., Peacock, S. J., & Prescott, H. C. (2020). Pathophysiology, transmission, diagnosis, and treatment of coronavirus disease 2019 (COVID-19): a review. Jama, 324(8), 782-793.

Williams, F. M., Fernández-Berrocal, P., Extremera, N., Ramos-Díaz, N., & Joiner, T. E. (2004). Mood regulation skill and the symptoms of endogenous and hopelessness depression in Spanish high school students. Journal of Psychopathology and Behavioral Assessment, 26(4), 233-240.

Wind, T. R., Rijkeboer, M., Andersson, G., & Riper, H. (2020). The COVID-19 pandemic: The 'black swan'for mental health care and a turning point for e-health. Internet interventions, 20.

Xiong, J., Lipsitz, O., Nasri, F., Lui, L. M., Gill, H., Phan, L., . . . Majeed, A. (2020). Impact of COVID-19 pandemic on mental health in the general population: A systematic review. Journal of affective disorders.

Znoj, H., & Schnyder, U. (2014). Verbitterungsfragebogen Kurzversion. University of Bern.

2.6 Article 6: Age, motivation, and emotion-regulation skills predict treatment outcome in an internet-based self-help intervention for COVID-19 related psychological distress

Brog, N. A., Hegy, J. K., Berger, T., & Znoj, H. (under review). *Age, motivation, and emotion-regulation skills predict treatment outcome in an internet-based self-help intervention for COVID-19 related psychological distress*.

Age, motivation, and emotion-regulation skills predict treatment outcome in an internet-based self-help intervention for COVID-19 related psychological distress

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Abstract

Introduction: First evidence suggests that internet-based self-help interventions effectively reduce COVID-19 related psychological distress. However, it is yet unclear which participant characteristics are associated with better treatment outcomes. Therefore, we conducted secondary analyses on data from a randomized controlled trial investigating the efficacy of a 3-week internet-based self-help intervention for COVID-19 related psychological distress. We explored several predictors (sociodemographic variables, psychopathological variables, resource-related variables, and treatment-related variables) of treatment outcomes, which were defined as post-treatment depressive symptoms and post-treatment resilience.

Methods: In a total of 107 participants with at least mild depressive symptoms, possible predictor variables and treatment outcomes were assessed using self-report measures. In a first step, we performed a separate linear regression analysis for each potential predictor. In a second step, predictors meeting a significant threshold of $p < 0.05$ were entered in linear multiple regression models.

Results: The mean age of the participants was 40.36 years (SD = 14.59, range = 18-81 years) with the majority being female (n = 87, 81.3%). Younger age predicted lower post-treatment depressive symptoms. Additionally, higher motivation to use the intervention and better pre-treatment emotion regulation skills predicted higher post-treatment resilience.

Conclusion: The current study provides preliminary evidence regarding the relationship between participant characteristics and treatment outcome in internet-based self-help interventions for COVID-19 related distress. Our results suggest that under the circumstances surrounding COVID-19 such interventions might be particularly beneficial for young adults. Moreover,

focusing on participants' existing strengths might be a promising approach to promote resilience through internet-based self-help interventions.

Trial registration: ClinicalTrials.gov NCT04380909. Retrospectively registered on 8 May 2020.

Introduction

In March 2020, the World Health Organization (WHO) declared the COVID-19 (acute respiratory syndrome coronavirus 2; SARS-CoV-2) outbreak a pandemic (1). At the onset and during the COVID-19 pandemic, studies indicated a deterioration of mental health in the general population (2-6). In particular, evidence for an increase in depression and anxiety symptoms was found (7). For example, in a study in the USA, a tripling of the prevalence of depression symptoms in the general population during the COVID-19 pandemic was reported (8). Accordingly, mental health interventions mitigating a possible increase in psychological distress are needed. A promising approach is the use of internet-based self-help interventions since they do not require direct on-site contact and are easily scalable (9-11). Studies indicate that internet-based self-help interventions are an effective treatment option for various psychological problems, including depressive symptoms (12, 13). So far, few studies have investigated the efficacy of internet-based self-help interventions for COVID-19 related psychological distress in the general population. However, first results suggest that internet-based self-help interventions are efficacious in reducing COVID-19 related worry and associated symptoms (14), symptoms of depression, anxiety, and stress (15, 16), as well as in promoting resilience and emotion-regulation skills (17). Nonetheless, in one study, there was no significant reduction of depressive symptoms (17). Since there is still comparatively little research available, and it shows mixed results, it is important to find out who benefits from internet-based self-help for COVID-19 related psychological distress and who does not.

In the context of the COVID-19 pandemic, understanding the relationship between participant characteristics and treatment outcome is of particular interest since some studies point towards the need for tailoring interventions for specific risk populations (5, 7). Identifying

predictors of treatment outcomes in internet-based self-help for COVID-19 related psychological distress would allow interventions to be tailored to specific needs and thus improve intervention efficacy. Accordingly, knowledge of the predictors of treatment outcomes would inform how interventions could be improved for specific use in target populations or adapted for other target populations. For example, if age predicts treatment outcomes, interventions could be tailored and improved for specific age groups or adapted for those not yet reached. So far, potential risk factors for heightened psychological distress due to the COVID-19 pandemic include for example: pre-existing mental health problems (18-20), pre-existing physical health problems (19), younger age (21-24), identifying as non-binary (19), female gender (19-22), and difficulties in emotion regulation (25, 26).

However, to the best of our knowledge, no study to date has investigated predictors of treatment outcome in internet-based self-help interventions for COVID-19 related psychological distress. Therefore, to improve the understanding of the relationship between participant characteristics and treatment outcome in internet-based self-help for COVID-19 related psychological distress, we explored predictors of treatment outcome in an internet-based self-help intervention for COVID-19 related psychological distress called ROCO (17, 27). The efficacy of the ROCO intervention was evaluated in a randomized controlled trial, from which the data used in this study are drawn (17). The primary target of the ROCO intervention was a reduction of depressive symptoms. However, a considerable part of the intervention was also aimed at promoting resilience (27). Therefore, in the present study, we defined treatment outcomes as post-treatment depressive symptoms and post-treatment resilience. Based on the above mentioned previous research on possible risk factors for COVID-19 related psychological distress, we decided to explore sociodemographic variables (age, gender, and level of education),

psychopathological variables (ever having received a psychiatric diagnosis, previous or current psychotherapy, current medication, anxiety, stress, embitterment, loneliness, and mental and physical health quality), and resource-related variables (emotion regulation skills, optimism, and self-efficacy) as possible predictors. Moreover, we explored if treatment-related variables (motivation to use the self-help intervention, number of completed modules) predict treatment outcome.

Materials and Methods

Study Design

The data used in the current study were obtained in a parallel-group randomized controlled trial (RCT) investigating the efficacy of a short internet-based self-help intervention for COVID-19 related psychological distress called ROCO. In the RCT, an immediate treatment group was compared to a waiting control group, with both groups receiving care as usual (CAU; 17, 27). The protocol of the study was approved by the Ethics Committee of the Canton of Bern, and the trial was registered on ClinicalTrials.gov (NCT04380909).

For the present secondary analysis, data from both groups were combined, using the data of the respective treatment phase (immediate or delayed). The investigated predictors of post-treatment outcomes (depressive symptoms and resilience, respectively) were assessed before the respective treatment phase (i.e., for the immediate treatment group at baseline and for the waiting control group after the waiting period). Sociodemographic variables as well as information on previous or current psychological treatments (ever received a psychiatric diagnosis, prior experience with psychotherapy, current psychotherapy or medication intake) were collected for both groups at baseline.

Participants

We recruited German-speaking participants between April 2020 and February 2021, primarily through newspaper articles, internet forums on mental health, and advertisements on the internet. Interested participants registered on our study homepage and subsequently received the detailed study information. After providing informed consent, participants completed the online baseline assessment, consisting of questions concerning socio-demographic variables, previous or current psychological treatment, and various self-report questionnaires. The following inclusion and exclusion criteria were evaluated based on this baseline assessment: participants had to be at least 18 years of age, have access to the internet, show sufficient knowledge of the German language, provide an emergency address for the case of an acute crisis, and reach a minimum of 4 points on the Patient Health Questionnaire (PHQ; 28), which is interpreted as the presence of mild depressive symptoms. Participants were excluded if they reached a cut-off value of 8 points on the Suicide Behavior Questionnaire (SBQ-R; 29), which would indicate the presence of suicidal tendencies. Furthermore, participants reporting a known psychotic or bipolar disorder diagnosis were also excluded. A total of 107 participants met all the inclusion criteria and none of the exclusion criteria, thus constituting the current study sample. These participants were randomized in a 1:1 ratio to either the immediate treatment group or the waiting control group. Participants in the immediate treatment group received direct access to the 3-week internet-based ROCO intervention, whereas participants in the waiting control group had a waiting period of three weeks and then received access to the ROCO intervention (i.e., delayed treatment). Three weeks after randomization, all participants had to fill out a second assessment (post-treatment for the immediate treatment group; pre-treatment for the waiting control group).

All participants had to complete a third assessment six weeks after the randomization (follow-up for the immediate treatment group; post-treatment for the waiting control group).

Measures

All assessments were administered online and consisted of self-report questionnaires. We used the German versions of the self-report questionnaires.

Outcome measures

Depressive symptoms, the primary treatment target of the internet-based intervention, were measured with the PHQ-9 (28). The PHQ-9 is used to assess the severity of depressive symptoms. For this purpose, nine items are scored on a scale from $0 =$ not at all to $5 =$ nearly every day. The nine items correspond to the nine DSM-IV criteria for depression. From the nine items, a score is built: a score of 5 corresponds to mild depression, a score of 10 to moderate depression, a score of 15 to moderately severe depression, and a score of 20 to severe depression (30). In the present sample, the PHQ-9 had a satisfactory internal consistency (Cronbach's $\alpha =$ 0.72 at pre-treatment and Cronbach's $\alpha = 0.74$ at post-treatment).

A secondary treatment target of the internet-based intervention was to promote resilience. Resilience was measured with the Connor-Davidson Resilience Scale (CD-RISC; 31). In the present study, the 10-item version of the CD-RISC was used. The ten items are answered on a scale from $0 =$ not true at all to $4 =$ true nearly all of the time. Higher scores correspond to more resilience. In the present sample, the CD-RISC showed good internal consistency (Cronbach's α $= 0.88$ at pre-treatment and Cronbach's $\alpha = 0.90$ at post-treatment).

Predictors

We grouped possible predictor variables into four groups. The first group included sociodemographic variables, namely *age*, *gender*, and *level of education.*

The second group were psychopathological variables. At baseline, we assessed whether participants had *ever received a psychiatric diagnosis*, had *previously been in psychotherapy*, were *currently in psychotherapy*, and were *currently taking medication for mental health problems*. These variables were chosen as measures of pre-existing mental health problems and current psychological treatment needs, indicative of psychological burden (18, 32). At pre-treatment, we assessed several variables using self-report questionnaires. *Anxiety* and *stress* were measured by the corresponding subscales of the DASS-21 (33). Each subscale consists of seven items, which are answered on a scale from 0 = did not apply to me at all to 3 = applied to me very much or most of the time. On the anxiety subscale, a score of 4 represents mild anxiety, a score of 6 moderate anxiety, a score of 8 severe anxiety, and a score of 10 extremely severe anxiety. On the stress subscale, a score of 8 represents mild stress, a score of 10 moderate stress, a score of 13 severe stress, and a score of 17 extremely severe (34). In the present sample, the internal consistency at pre-treatment was close to satisfactory for the anxiety subscale (Cronbach's α = 0.68) and good for the stress subscale (Cronbach's α = 0.81). *Mental health quality* and *physical health quality* were assessed as measures of general health-related quality of life with the respective scales of the 12-Item Short-Form Health Survey (19, 35). Higher scores on the respective subscale indicate better mental health quality, respectively physical health quality. The SF-12 has a good test-retest reliability (36). *Embitterment* was measured with the 6-item version of the Bern Embitterment Inventory (37). Embitterment can be defined as the feeling of being disadvantaged by others and fate and might be a mental health reaction to the COVID-19 pandemic (38-40). Items are scored on a scale from 0 = I do not agree to 4 = I agree, with higher scores representing more embitterment (41). In the present sample, the internal consistency of the BEI at pre-treatment was good (Cronbach's α = 0.80). *Loneliness* was

assessed using the 9-item version of the UCLA Loneliness Scale (ULS; 42) since several studies

postulated a link between loneliness and mental health problems and the COVID-19 pandemic

has been reported to increase loneliness (43, 44). The items are answered on a scale from 1 =

never to 4 = often, with higher scores indicating more loneliness. In the present sample, the

internal consistency of the ULS at pre-treatment was good (Cronbach's α = 0.85).

The third group of predictor variables, which we subsumed under the umbrella term

resources, were assessed at pre-treatment. *Self-efficacy* was assessed using the General Self-

Efficacy Scale (GSE; 45). The 10 items are scored on a scale from 1 = not at all true to 4 =

exactly true, with higher scores indicating more self-efficacy (45). In the present sample, the

internal consistency of the GSE at pre-treatment was good (Cronbach's α = 0.89). *Optimism* was

assessed with the Life Orientation Test Revised (LOT-R; 46). The total score of the 10-item

LOT-R is built from six items, since four items are filler items. A higher score indicates more

optimism. The items are answered on a scale from 0 = strongly disagree to 4 = strongly agree

(46). In the present sample, the internal consistency of the LOT-R at pre-treatment was good

(Cronbach's α = 0.84). *Emotion-regulation skills* were assessed with the Self-report measure for

the assessment of emotion regulation skills (SEK-27; 47). The 27 items of the SEK-27 are

answered on a scale from 0 = never to 4= (almost) always, with higher scores corresponding to

better emotion-regulation skills (47). In the present sample, the internal consistency for the SEK-

27 at pre-treatment was excellent (Cronbach's α = 0.93).

Finally, the fourth group of predictor variables were *treatment-related variables*.

Motivation to use the internet-based intervention was assessed at baseline with one item (Please

indicate your motivation to use the ROCO program in general). Participants could rate their

motivation with a regulator from 0 = no motivation at all to 100 = greatest possible motivation.

The *number of completed modules* was measured after the treatment. It could range from 0 (no module completed) to 6 (all modules completed).

Description of intervention

The internet-based self-help intervention ROCO was aimed at persons experiencing COVID-19 related psychological distress. The acronym ROCO stands for resilience and optimism during COVID-19. The 3-week intervention consisted of six thematic modules, an introduction, and a conclusion. Additionally, the intervention comprised a page with information on what to do in an acute crisis, including a list of emergency contacts, a page with an overview of the weekly exercises, and a page with a symptom-tracking questionnaire, allowing participants to track their self-reported symptoms. The six thematic modules were based on cognitive-behavioral therapy and included texts, videos, graphics, and exercises. Each thematic module had a specific focus: in module 1, psychoeducation about COVID-19 related psychological distress was given. In module 2, participants learned about emotions and emotion regulation. In module 3, the identification and restructuring of thought patterns were addressed. In module 4, participants acquired knowledge about several possibilities to promote resilience. In module 5, relaxation techniques and sleep hygiene were discussed. Finally, in module 6, the topics of self-care and personal growth were approached. For a more detailed description of the intervention, see the study protocol of the ROCO RCT (27). Participants were advised to work through two modules per week. However, the participants could decide for themselves which modules they wanted to work on and in which order. A module took about 40 to 80 minutes to complete. Since the internet-based self-help program offered guidance on demand, the participants had the possibility to contact a psychologist via a chat function. The psychologist answered within three working days. Otherwise, there was no scheduled contact.

Statistical Analysis

All analyses were conducted using IBM SPSS Statistics (version 25). Independent

samples *t*-tests and χ^2-tests (for nominal data) were performed to examine group differences at

baseline and pre-treatment. In a first step, potential predictors were identified using simple linear

regression analyses. For each potential predictor a separate linear regression analysis was

performed as follows: the potential predictor (e.g., age) was entered as predictor, the post-

treatment score of the outcome (depressive symptoms or resilience) was entered as dependent

variable, and the pre-treatment score of the respective outcome (e.g. depressive symptoms) was

defined as covariate. We predetermined that predictors had to reach a *p*-value below 0.05 to be

included in the subsequent multiple regression analyses. In a second step, a multiple regression

analysis was performed for each outcome with the predictors identified in step 1 entered as

predictors and the pre-treatment score of the respective outcome entered as covariate. To account

for possible group effects, we additionally tested whether group (immediate vs. delayed

treatment) was a significant predictor for the outcome while using the pre-treatment values of the

respective outcome as covariate. If the group was a significant predictor ($p < 0.050$), it was

added as covariate in the multiple regression analysis of the respective outcome. We did not

replace missing data in the predictor variables. Hence only participants with complete data sets

were considered for the respective outcomes.

Results

Sample characteristics

The total sample consisted of 107 German-speaking participants. On average, they were

40.36 years old ($SD = 14.59$, range = 18-81 years) and the majority were female ($n = 87$, 81.3%),

had a university degree ($n = 64$, 59.8%) and previous experience with psychological treatment (n

= 68, 63.6 %). Overall, 28 participants (26.2%) were in concurrent psychological treatment and 24 participants (22.4%) were taking medication for psychological problems at baseline. The participants showed, on average, moderate depressive symptoms ($M = 10.37$, $SD = 4.18$) and mild anxiety and stress symptoms ($M = 4.33$, $SD = 3.26$; $M = 8.80$, $SD = 4.10$) at pre-treatment. Approximately one third of the participants ($n = 36$, 33.6 %) reported having received a psychiatric diagnosis at some point in their lives. Baseline or pre-treatment scores of the predictor variables and outcome measures are displayed in Table 1. There was a significant group difference in terms of education ($\chi^2_{(1)} = 5.055$, $p = 0.025$), indicating that participants in the immediate treatment group had a lower average level of education. Moreover, participants in the delayed treatment group completed significantly fewer modules of the intervention than participants in the immediate intervention group ($t_{(104.1)}= 2.719$, $p = 0.009$). Additionally, the delayed treatment group showed markedly lower pre-treatment depression scores compared to the immediate treatment group (immediate treatment group M (SD) = 11.13 (4.36) vs. delayed treatment group M (SD) = 9.60 (3.89)). However, the group difference was not significant ($t_{(102.1)}= 1.908$, $p = 0.055$).

Table 1

Predictors and outcome measures at baseline or pre-treatment, overall and divided by group.

	Total	Immediate treatment group	Delayed treatment group	Statistic
	$N = 107$	$n = 53$	$n = 54$	
Socio-demographic variables				
Age, *M (SD)*	40.36 (14.59)	40.68 (15.55)	40.04 (13.73)	$t_{(105)}= 0.227, p = 0.819^b$
Female, n (%)	87 (81.3)	46 (86.8)	41 (75.9)	$X^2_{(1)} = 2.078, p = 0.149$
University, n (%)	64 (59.8)	26 (49.1)	38 (70.4)	$X^2_{(1)} = 5.055, p = 0.025$
Psychopathological variables				
Psychiatric diagnosis, n (%)	36 (33.6)	21 (39.6)	15 (27.8)	$X^2_{(1)} = 1.681, p = 0.195$
Psychological treatment				
Previous, n (%)	68 (63.6)	38 (71.7)	30 (55.6)	$X^2_{(1)} = 3.009, p = 0.083$
Current, n (%)	28 (26.2)	14 (26.4)	14 (25.9)	$X^2_{(1)} = 0.003, p = 0.954$
Current medication, n (%)	24 (22.4)	14 (26.4)	10 (18.5)	$X^2_{(1)} = 0.966, p = 0.326$
	$n^a = 105$	$n = 52$	$n = 53$	
Anxiety (DASS-21), M (SD)	4.33 (3.26)	4.43 (3.51)	4.23 (3.01)	$t_{(101.3)}= 0.319, p = 0.741^b$
	$n = 105$		$n = 52$	
Stress (DASS-21), M (SD)	8.80 (4.10)	9.42 (4.03)	8.17 (4.12)	$t_{(103)}= 1.562, p = 0.119^b$
	$n = 105$		$n = 52$	
Embitterment (BEI), M (SD)	9.12 (5.04)	8.75 (4.88)	9.50 (5.22)	$t_{(101)}= -0.749, p = 0.440^b$
	$n = 103$		$n = 50$	
Loneliness (ULS), M (SD)	20.77 (4.46)	21.26 (4.82)	20.27 (4.04)	$t_{(100.6)}= 1.147, p = 0.261^b$
	$n = 105$		$n = 52$	

Mental health quality (SF-12), M, (SD)	31.66 (9.12) n = 105	31.10 (9.10)	32.23 (9.20) n = 52	$t_{(103)}$= -0.636, p =0.528[b]
Physical health quality (SF-12), M (SD)	53.65 (7.68) n = 105	53.43 (8.79)	53.87 (6.43) n = 52	$t_{(95.3)}$= -0.292, p =0.779[b]
Resources				
Optimism (LOT-R), M (SD)	14.33 (4.89) n = 103	14.43 (5.04)	14.22 (4.73) n = 50	$t_{(101)}$= 0.222, p =0.820[b]
Self-efficacy (GSE), M (SD)	26.29 (4.47) n = 104	25.91 (4.47)	26.69 (4.47) n = 51	$t_{(102)}$= -0.890, p =0.369[b]
Emotion regulation skills (SEK-27), M (SD)	62.70 (15.97) n = 103	62.64 (15.45)	62.76 (16.65) n = 50	$t_{(101)}$= -0.037, p =0.976[b]
Treatment-related variables				
Number of completed modules, M (SD)	3.51 (2.47)	4.15 (2.27)	2.89 (2.53)	$t_{(104.1)}$= 2.719, p =0.009[b]
Motivation, M (SD)	84.26 (14.14)	83.09 (17.20)	85.41 (10.35)	$t_{(85.0)}$= -0.841, p =0.417[b]
Outcome measures				
Depressive symptoms (PHQ-9), M (SD)	10.37 (4.18) n = 105	11.13 (4.36)	9.60 (3.89) n = 52	$t_{(102.1)}$= 1.908, p =0.055[b]
Resilience (CD-RISC), M (SD)	22.47 (6.68) n = 103	21.87 (6.62)	23.10 (6.75) n = 50	$t_{(101)}$= -0.935, p =0.359[b]

Notes. M, Mean; *SD*, standard deviation; DASS-21, Depression Anxiety Stress Scale; BEI, Bern Embitterment Inventory; ULS, UCLA Loneliness Scale; SF-12, Short-Form Health Survey; LOT-R O, Life Orientation Test Revised; GSE, General Self-Efficacy Scale; SEK-27, Self-report Measure to measure emotion regulation skills; PHQ-9, Patient Health Questionnaire; CD-RISC, Connor-Davidson Resilience Scale.

[a] *N's* range from 103 to 107 due to occasional missing data. If *n* is not reported, it equals the number in the column header.

[b] Bootstrap 1000 samples.

Identifying predictors of post-treatment depressive symptoms and resilience

In a first step, variables predicting post-treatment depressive symptoms and resilience were identified using simple linear regressions. We controlled for pre-treatment scores of the corresponding outcome measures (depressive symptoms or resilience). The results of the single predictor analysis are displayed in Table 2. In a second step, the variables that met the previously defined threshold of a p-value below 0.05 were included in a multiple regression model (see Tables 3 and 4). All models used centered predictor variables (grand mean-centered) to anticipate possible multicollinearity. Since the variable group (immediate vs. delayed treatment) was a significant covariate for resilience ($\Delta R^2 = 0.034$, $\beta = -0.184$, $p = 0.013$), it was entered in the respective multiple regression.

Table 2

Single-predictor linear regression analysis with post-treatment depressive symptoms respectively

post-treatment resilience as dependent variable controlling for pre-treatment depressive

symptoms, respectively pre-treatment resilience.

Predictors	Depressive symptoms (PHQ-9)			Resilience (CD-RSIC)		
	ΔR^2	β	p	ΔR^2	β	p
Socio-demographic variables						
Age	0.066	0.259	0.006	0.004	0.066	0.382
Female Gender	0.019	-0.138	0.145	0.009	0.096	0.207
University	0.022	0.148	0.119	0.002	0.043	0.571
Psychopathological variables						
Anxiety (DASS-21)	0.044	0.246	0.026	0.000	0.005	0.950
Stress (DASS-21)	0.036	0.238	0.044	0.000	0.018	0.821
Embitterment (BEI)	0.001	0.030	0.767	0.011	0.113	0.158
Loneliness (ULS)	0.006	0.083	0.422	0.009	0.102	0.200
Mental health quality (SF-12)	0.000	0.012	0.925	0.000	0.021	0.794
Physical health quality (SF-12)	0.031	-0.178	0.063	0.001	-0.026	0.737
Psychiatric diagnosis	0.056	-0.237	0.011	0.000	0.002	0.982
Previous psychotherapy	0.069	-0.263	0.005	0.005	0.070	0.353
Current psychotherapy	0.063	-0.251	0.007	0.007	0.086	0.254
Current medication	0.005	-0.070	0.475	0.002	-0.045	0.573
Resources						
Self-efficacy (GSE)	0.011	-0.114	0.276	0.007	0.139	0.267
Optimism (LOT_R)	0.010	-0.103	0.302	0.000	0.008	0.934
Emotion regulation skills (SEK-27)	0.008	-0.103	0.349	0.024	0.189	0.037
Treatment-related variables						
Number of completed modules	0.026	-0.162	0.086	0.003	0.054	0.475
Motivation	0.020	0.141	0.135	0.027	0.163	0.030

Notes. Block one: pre-treatment depressive symptoms ($R^2 = 0.297, \beta = 0.545, p < 0.001$), respectively pre-treatment

resilience ($R^2 = 0.580, \beta = 0.762, p < 0.001$). Block two: predictor variables. PHQ-9, Patient Health Questionnaire;

CD-RISC, Connor-Davidson Resilience Scale; DASS-21, Depression Anxiety Stress Scale; BEI, Bern Embitterment

Inventory; ULS, UCLA Loneliness Scale; SF-12, Short-Form Health Survey; GSE, General Self-Efficacy Scale;

LOT-R O, Life Orientation Test Revised; SEK-27, Self-report Measure to measure emotion regulation skills.

Predictors of post-treatment depressive symptoms in multiple regression

Within the first multiple linear regression, we examined predictors for post-treatment depressive symptoms (see Table 3). The age of the participants at baseline was a significant predictor of post-treatment depressive symptoms (b (SE) = 0.043 (0.020), p = 0.032). The older the participants were, the higher their depressive symptoms were post-treatment.

Table 3

Predictors of the post-treatment depressive symptoms (multiple regression).

Predictors	Depressive symptoms		
	b (SE)	t	p
Pre-treatment depressive symptoms	0.299 (0.094)	3.193	0.002
Age	0.043 (0.020)	2.184	0.032
Anxiety (DASS-21)	0.179 (0.114)	1.565	0.122
Stress (DASS-21)	0.188 (0.096)	1.971	0.053
Psychiatric diagnosis	-0.763 (0.704)	-1.084	0.282
Previous psychotherapy	-1.313 (0.726)	-1.808	0.075
Current psychotherapy	-0.864 (0.768)	-1.125	0.264

Notes. The model was significant (F (7,73) = 10.715, p < 0.001), adjusted R^2 = 0.459; the model includes an intercept (b = 10.304, SE = 0.62, t = 16.650, p < 0.001); predictors were selected based on single-predictor regressions (Table 2); predictors were grand-mean centered to avoid multicollinearity.

Predictors of post-treatment resilience in multiple regression

Table 4 displays the results of the second multiple linear regression, in which post-treatment resilience was the outcome. Both motivation at baseline (b (SE) = 0.092 (0.032), p = 0.006) and pre-treatment emotion-regulation skills (b (SE) = 0.072 (0.036), p = 0.047) predicted

post-treatment resilience. The higher the motivation of the participants to use the intervention was, the higher their resilience was post-treatment. Likewise, the better the emotion regulation skills of the participants were pre-treatment, the higher their resilience was post-treatment.

Table 4

Predictors of the post-treatment resilience (multiple regression).

Predictors	Resilience		
	b (SE)	*t*	*p*
Pre-treatment resilience	0.691 (0.086)	8.007	< 0.001
Group (immediate vs. delayed treatment)	-2.465 (0.917)	-2.687	0.009
Emotion regulation skills (SEK-27)	0.072 (0.036)	2.023	0.047
Motivation	0.092 (0.032)	2.851	0.006

Notes. The model was significant ($F_{(4,71)} = 35.858$, $p < 0.001$), adjusted $R^2 = 0.650$; the model includes an intercept (b = 23.790, SE = 0.61, t = 38.857, p < 0.001); predictors were selected based on single-predictor regressions (Table 2); predictors were grand-mean centered to avoid multicollinearity.

Discussion

In the present study, we aimed to identify predictors of treatment outcome in users of an internet-based self-help intervention for COVID-19-related psychological distress. With regard to depressive symptoms, being younger predicted lower depressive symptoms after the 3-week intervention. With regard to resilience, higher motivation to use the intervention and better emotion regulation skills pre-treatment predicted higher resilience after the 3-week intervention.

We found that higher age was associated with worse treatment outcomes regarding depressive symptoms. This finding is inconsistent with previous research on predictors of internet-based self-help interventions for depression, in which age was not predictive of

treatment outcome (48-52). The present finding is not straightforward to explain but could be related to the specific circumstances of the COVID-19 pandemic. A possible explanation could be a differential influence of various COVID-19-related stressors on psychological distress depending on age and that the intervention under study provided better support in dealing with certain stressors. For example, in a sample of 22-year-olds, secondary consequences of the COVID-19 pandemic, such as disruption of lifestyle or economic disruption were more strongly associated with psychological distress than COVID-19-related health risk exposures (53). Moreover, in one study, avoidant coping moderated the relationship between COVID-19 related psychological distress and depressive symptoms more strongly in younger adults compared to older adults (54). Therefore, younger adults might benefit more from an intervention fostering adaptive coping than older adults. Given that research increasingly suggests that young adults are particularly affected mentally by the COVID-19 pandemic, the present finding is promising, despite the difficult explanation (21-24).

Regarding resilience, we found that higher motivation to use the intervention and better emotion regulation skills pre-treatment predicted better treatment outcome. To the best of our knowledge, there have been no studies examining predictors of treatment outcome in interventions promoting resilience, let alone internet-based interventions. However, in an internet-based self-help intervention for stress, higher motivation seemed to predict better adherence (55). Accordingly, it could be assumed that the effect of higher motivation on treatment outcome regarding resilience is mediated by adherence in our study as well. Yet, this assumption is not supported by our data, as the number of completed modules did not predict the treatment outcome in terms of resilience (b (SE) = 0.162 (0.226), p = 0.475). However, these results could be attributed to the fact that we measured adherence only by the number of

completed modules. Some studies point out that adherence involves much more than mere technological usage (56, 57). Therefore, it could be possible that highly motivated participants were otherwise more engaged with the internet-based intervention, for example, by addressing the content of the intervention in more depth or implementing it more thoroughly in their daily lives, which in turn could have improved treatment outcome.

In addition to motivational conditions, pre-treatment emotion regulation skills also appear to predict how much participants benefit from an internet-based intervention for COVID-19 related psychological distress in terms of resilience. The better treatment outcome regarding resilience in participants with better pre-treatment emotion regulation skills could be caused by so-called capitalization. Capitalization describes the fact that pre-existing strengths of patients are reinforced and built on in therapy (58). In one study, tailoring treatment by focusing on patients' respective strengths rather than on their respective deficits led to better treatment outcomes in depressed patients (59). Since the intervention under study focuses, among other aspects, on building emotion regulation skills, it could be argued that emotion regulation skills were capitalized in participants with better pre-treatment emotion regulation skills. Previous research found that emotion regulation skills are associated with higher resilience (60) and better emotional adjustment (61). Therefore, capitalizing emotion regulation skills might lead to benefits in resilience. In conclusion, it appears that in the present study, participants with higher pre-treatment resources (motivation or emotion-regulation skills) benefited more from the internet-based self-help intervention regarding resilience.

In the current study, multiple possible predictor variables did not predict post-treatment depressive symptoms and resilience. For example, female gender predicted neither treatment outcome. This finding is consistent with studies that found no effect of female gender on

treatment outcome (48-50, 62). However, there are also some studies that have shown that female gender predicted better treatment outcome (63-65).

The current study comes with several limitations. First, our sample was relatively small for predictor analysis. The sample might have been underpowered since predictor effects in internet-based interventions tend to be small. Moreover, as only participants with complete data sets were included in the analysis, sample size was further reduced for some outcomes due to drop-out. Second, participants in the delayed treatment group completed significantly less modules than participants in the immediate treatment group ($t_{(104.1)}$= 2.719, p =0.009). One possible reason for this result could be that the burden of the participants in the delayed treatment group has already decreased during the waiting period. Accordingly, there is a clear, albeit not significant, difference in the pre-treatment depression scores (immediate treatment group M (SD) = 11.13 (4.36) vs. delayed treatment group M (SD) = 9.60 (3.89)). The current sample might have been already less burdened at pre-treatment, and therefore might not be representative of people with COVID-19 related psychological distress actively seeking support. Third, we relied only on self-report outcome measures and did not conduct a clinical assessment. Accordingly, responses could be subjectively biased. This could particularly concern information on psychological burden.

Conclusion

Despite the limitations mentioned above, the current study gives preliminary evidence on the relationship between participant characteristics and treatment outcome in internet-based self-help interventions for COVID-19 related distress. One promising finding is that young adults, who can be considered a psychologically vulnerable group in the COVID-19 pandemic, seem to benefit from such an intervention in terms of depressive symptoms. Moreover, participants with

higher motivation and better pre-treatment emotion regulation skills seemed to be able to build on their strengths and showed better treatment outcome in terms of resilience. Therefore, it could be beneficial to tailor interventions to respective strengths of the participants in order to promote resilience. Also, further studies are needed to make informed decisions about the relationship of participant characteristics and treatment outcome in internet-based self-help interventions for COVID-19 related psychological distress.

Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Author Contributions

NAB drafted the manuscript and was responsible for its conceptualization, methodology, formal analysis, data curation, and writing. JKH was responsible for data curation and writing-reviewing and editing. TB and HJ were responsible for project administration, resources and writing-reviewing and editing.

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Supplementary Material

Not applicable, no supplementary material is provided.

Data Availability Statement

Data are available from the first author upon reasonable request.

References

1. Wiersinga WJ, Rhodes A, Cheng AC, Peacock SJ, Prescott HC. Pathophysiology, transmission, diagnosis, and treatment of coronavirus disease 2019 (COVID-19): a review. Jama. 2020;324(8):782-93.

2. Wang C, Pan R, Wan X, Tan Y, Xu L, Ho CS, et al. Immediate psychological responses and associated factors during the initial stage of the 2019 coronavirus disease (COVID-19) epidemic among the general population in China. International journal of environmental research and public health. 2020;17(5):1729.

3. Rajkumar RP. COVID-19 and mental health: A review of the existing literature. Asian journal of psychiatry. 2020:102066.

4. Qiu J, Shen B, Zhao M, Wang Z, Xie B, Xu Y. A nationwide survey of psychological distress among Chinese people in the COVID-19 epidemic: implications and policy recommendations. General psychiatry. 2020;33(2).

5. Breslau J, Finucane ML, Locker AR, Baird MD, Roth EA, Collins RL. A longitudinal study of psychological distress in the United States before and during the COVID-19 pandemic. Preventive medicine. 2021;143:106362.

6. Xiong J, Lipsitz O, Nasri F, Lui LM, Gill H, Phan L, et al. Impact of COVID-19 pandemic on mental health in the general population: A systematic review. Journal of affective disorders. 2020.

7. Luo M, Guo L, Yu M, Wang H. The Psychological and Mental Impact of Coronavirus Disease 2019 (COVID-19) on Medical Staff and General Public–A Systematic Review and Meta-analysis. Psychiatry Research. 2020:113190.

8. Ettman CK, Abdalla SM, Cohen GH, Sampson L, Vivier PM, Galea S. Prevalence of depression symptoms in US adults before and during the COVID-19 pandemic. JAMA network open. 2020;3(9):e2019686-e.

9. Halder S. COVID-19: Psychological Impact and Psychotherapeutic Intervention. EC Psychology and Psychiatry. 2020;9:32-5.

10. Soklaridis S, Lin E, Lalani Y, Rodak T, Sockalingam S. Mental health interventions and supports during COVID-19 and other medical pandemics: A rapid systematic review of the evidence. General hospital psychiatry. 2020;66:133-46.

11. Wind TR, Rijkeboer M, Andersson G, Riper H. The COVID-19 pandemic: The 'black swan'for mental health care and a turning point for e-health. Internet interventions. 2020;20.

12. Andersson G, Titov N. Advantages and limitations of Internet-based interventions for common mental disorders. World Psychiatry. 2014;13(1):4-11.

13. Cuijpers P, Donker T, Johansson R, Mohr DC, van Straten A, Andersson G. Self-guided psychological treatment for depressive symptoms: a meta-analysis. PloS one. 2011;6(6):e21274.

14. Wahlund T, Mataix-Cols D, Lauri KO, de Schipper E, Ljótsson B, Aspvall K, et al. Brief online cognitive behavioural intervention for dysfunctional worry related to the COVID-19 pandemic: a randomised controlled trial. Psychotherapy and Psychosomatics. 2021;90(3):191-9.

15. Al-Alawi M, McCall RK, Sultan A, Al Balushi N, Al-Mahrouqi T, Al Ghailani A, et al. Efficacy of a six-week-long therapist-guided online therapy versus self-help internet-based therapy for COVID-19–induced anxiety and depression: open-label, pragmatic, randomized controlled trial. JMIR mental health. 2021;8(2):e26683.

16. Aminoff V, Sellén M, Sörliden E, Ludvigsson M, Berg M, Andersson G. Internet-Based Cognitive Behavioral Therapy for Psychological Distress Associated With the COVID-19 Pandemic: A Pilot Randomized Controlled Trial. Frontiers in Psychology. 2021;12:1998.

17. Brog NA, Hegy JK, Berger T, Znoj H. Effects of an internet-based self-help intervention for psychological distress due to COVID-19: results of a randomized controlled trial. Manuscript submitted for publication. 2021.

18. Asmundson GJ, Paluszek MM, Landry CA, Rachor GS, McKay D, Taylor S. Do pre-existing anxiety-related and mood disorders differentially impact COVID-19 stress responses and coping? Journal of anxiety disorders. 2020;74:102271.

19. Alonzi S, La Torre A, Silverstein MW. The psychological impact of preexisting mental and physical health conditions during the COVID-19 pandemic. Psychological trauma: theory, research, practice, and policy. 2020;12(S1):S236.

20. Mazza C, Ricci E, Biondi S, Colasanti M, Ferracuti S, Napoli C, et al. A nationwide survey of psychological distress among Italian people during the COVID-19 pandemic: immediate psychological responses and associated factors. International journal of environmental research and public health. 2020;17(9):3165.

21. Li LZ, Wang S. Prevalence and predictors of general psychiatric disorders and loneliness during COVID-19 in the United Kingdom. Psychiatry research. 2020;291:113267.

22. Kimhi S, Marciano H, Eshel Y, Adini B. Resilience and demographic characteristics predicting distress during the COVID-19 crisis. Social Science & Medicine. 2020;265:113389.

23. Birditt KS, Turkelson A, Fingerman KL, Polenick CA, Oya A. Age differences in stress, life changes, and social ties during the COVID-19 pandemic: Implications for psychological well-being. The Gerontologist. 2021;61(2):205-16.

24. Kowal M, Coll-Martín T, Ikizer G, Rasmussen J, Eichel K, Studzińska A, et al. Who is the most stressed during the COVID-19 pandemic? Data from 26 countries and areas. Applied Psychology: Health and Well-Being. 2020;12(4):946-66.

25. Tyra AT, Griffin SM, Fergus TA, Ginty AT. Individual differences in emotion regulation prospectively predict early COVID-19 related acute stress. Journal of Anxiety Disorders. 2021;81:102411.

26. Panayiotou G, Panteli M, Leonidou C. Coping with the invisible enemy: The role of emotion regulation and awareness in quality of life during the COVID-19 pandemic. Journal of Contextual Behavioral Science. 2021;19:17-27.

27. Brog NA, Hegy JK, Berger T, Znoj H. An internet-based self-help intervention for people with psychological distress due to COVID-19: study protocol for a randomized controlled trial. Trials. 2021;22(1):171.

28. Löwe B, Spitzer RL, Zipfel S, Herzog W. Komplettversion und Kurzform. Pfizer; 2002.

29. Osman A, Bagge CL, Gutierrez PM, Konick LC, Kopper BA, Barrios FX. The Suicidal Behaviors Questionnaire-Revised (SBQ-R): validation with clinical and nonclinical samples. Assessment. 2001;8(4):443-54.

30. Kroenke K, Spitzer RL. The PHQ-9: a new depression diagnostic and severity measure. Psychiatric annals. 2002;32(9):509-15.

31. Connor KM, Davidson JR. Development of a new resilience scale: The Connor-Davidson resilience scale (CD-RISC). Depression and anxiety. 2003;18(2):76-82.

32. Daly M, Robinson E. Psychological distress and adaptation to the COVID-19 crisis in the United States. Journal of psychiatric research. 2021;136:603-9.

33. Lovibond PF, Lovibond SH. The structure of negative emotional states: Comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. Behaviour research and therapy. 1995;33(3):335-43.

34. Gomez F. A guide to the depression, anxiety and stress scale (DASS 21). Central and Eastern Sydney primary health networks. 2016.

35. Ware Jr JE, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Medical care. 1996:220-33.

36. Gandek B, Ware JE, Aaronson NK, Apolone G, Bjorner JB, Brazier JE, et al. Cross-validation of item selection and scoring for the SF-12 Health Survey in nine countries: results from the IQOLA Project. Journal of clinical epidemiology. 1998;51(11):1171-8.

37. Znoj H, Schnyder U. Verbitterungsfragebogen Kurzversion. Bern: University of Bern; 2014.

38. Znoj H, Abegglen S, Buchkremer U, Linden M. The embittered mind. Journal of individual differences. 2016.

39. Muschalla B, Vollborn C, Sondhof A. Embitterment as a Specific Mental Health Reaction during the Coronavirus Pandemic. Psychopathology. 2021;54(5):232-41.

40. De Sousa A, D'souza R, editors. Embitterment: The Nature of the Construct and Critical Issues in the Light of COVID-19. Healthcare; 2020: Multidisciplinary Digital Publishing Institute.

41. Znoj H. BVI. Berner Verbitterungs-Inventar.: Hogrefe; 2008.

42. Luhmann M, Bohn J, Holtmann J, Koch T, Eid M. I'm lonely, can't you tell? Convergent validity of self-and informant ratings of loneliness. Journal of Research in Personality. 2016;61:50-60.

43. Lee CM, Cadigan JM, Rhew IC. Increases in loneliness among young adults during the COVID-19 pandemic and association with increases in mental health problems. Journal of Adolescent Health. 2020;67(5):714-7.

44. Okruszek L, Aniszewska-Stańczuk A, Piejka A, Wiśniewska M, Żurek K. Safe but lonely? Loneliness, mental health symptoms and COVID-19. 2020.

45. Jerusalem M, Schwarzer R. SWE-Skala zur Allgemeinen Selbstwirksamkeitserwartung. 2003.

46. Glaesmer H, Hoyer J, Klotsche J, Herzberg PY. Die deutsche version des Life-Orientation-Tests (LOT-R) zum dispositionellen Optimismus und Pessimismus. Zeitschrift für Gesundheitspsychologie. 2008;16(1):26-31.

47. Berking M, Znoj H. SEK-27. Fragebogen zur standardisierten Selbsteinschätzung emotionaler Kompetenzen [Verfahrensdokumentation aus PSYNDEX Tests-Nr. 9005957, Fragebogen und Auswertungsanweisung]. 2011 ed. (Hrsg.) ETTZ, editor: In Leibniz-Zentrum für Psychologische Information und Dokumentation (ZPID).

48. Niles AN, Axelsson E, Andersson E, Hedman-Lagerlöf E, Carlbring P, Andersson G, et al. Internet-based cognitive behavior therapy for depression, social anxiety disorder, and panic disorder: Effectiveness and predictors of response in a teaching clinic. Behaviour Research and Therapy. 2021;136:103767.

49. Høifødt RS, Mittner M, Lillevoll K, Katla SK, Kolstrup N, Eisemann M, et al. Predictors of response to Web-based cognitive behavioral therapy with high-intensity face-to-face

therapist guidance for depression: a Bayesian analysis. Journal of medical Internet research. 2015;17(9):e4351.

50. Warmerdam L, Van Straten A, Twisk J, Cuijpers P. Predicting outcome of Internet-based treatment for depressive symptoms. Psychotherapy Research. 2013;23(5):559-67.

51. Hobbs MJ, Joubert AE, Mahoney AE, Andrews G. Treating late-life depression: Comparing the effects of internet-delivered cognitive behavior therapy across the adult lifespan. Journal of affective disorders. 2018;226:58-65.

52. Schneider BC, Schröder J, Berger T, Hohagen F, Meyer B, Späth C, et al. Bridging the "digital divide": A comparison of use and effectiveness of an online intervention for depression between Baby Boomers and Millennials. Journal of affective disorders. 2018;236:243-51.

53. Shanahan L, Steinhoff A, Bechtiger L, Murray AL, Nivette A, Hepp U, et al. Emotional distress in young adults during the COVID-19 pandemic: evidence of risk and resilience from a longitudinal cohort study. Psychological medicine. 2020:1-10.

54. Minahan J, Falzarano F, Yazdani N, Siedlecki KL. The COVID-19 pandemic and psychosocial outcomes across age through the stress and coping framework. The Gerontologist. 2021;61(2):228-39.

55. Alfonsson S, Olsson E, Hursti T. Motivation and treatment credibility predicts dropout, treatment adherence, and clinical outcomes in an internet-based cognitive behavioral relaxation program: a randomized controlled trial. Journal of medical Internet research. 2016;18(3):e52.

56. Ryan C, Bergin M, Wells JS. Theoretical perspectives of adherence to web-based interventions: a scoping review. International journal of behavioral medicine. 2018;25(1):17-29.

57. Sieverink F, Kelders SM, van Gemert-Pijnen JE. Clarifying the concept of adherence to eHealth technology: systematic review on when usage becomes adherence. Journal of medical Internet research. 2017;19(12):e8578.

58. Flückiger C, Caspar F, Holtforth MG, Willutzki U. Working with patients' strengths: A microprocess approach. Psychotherapy Research. 2009;19(2):213-23.

59. Cheavens JS, Strunk DR, Lazarus SA, Goldstein LA. The compensation and capitalization models: A test of two approaches to individualizing the treatment of depression. Behaviour research and therapy. 2012;50(11):699-706.

60. Min J-A, Yu JJ, Lee C-U, Chae J-H. Cognitive emotion regulation strategies contributing to resilience in patients with depression and/or anxiety disorders. Comprehensive psychiatry. 2013;54(8):1190-7.

61. Berking M, Orth U, Wupperman P, Meier LL, Caspar F. Prospective effects of emotion-regulation skills on emotional adjustment. Journal of Counseling Psychology. 2008;55(4):485.

62. Vernmark K, Lenndin J, Bjärehed J, Carlsson M, Karlsson J, Öberg J, et al. Internet administered guided self-help versus individualized e-mail therapy: A randomized trial of two versions of CBT for major depression. Behaviour research and therapy. 2010;48(5):368-76.

63. Spek V, Nyklíček I, Cuijpers P, Pop V. Predictors of outcome of group and internet-based cognitive behavior therapy. Journal of affective disorders. 2008;105(1-3):137-45.

64. Clarke G, Kelleher C, Hornbrook M, DeBar L, Dickerson J, Gullion C. Randomized effectiveness trial of an Internet, pure self-help, cognitive behavioral intervention for depressive symptoms in young adults. Cognitive behaviour therapy. 2009;38(4):222-34.

65. Andersson G, Carlbring P, Rozental A. Response and remission rates in internet-based cognitive behavior therapy: an individual patient data meta-analysis. Frontiers in psychiatry. 2019;10:749.

3 General Discussion

Even though most people experience stressful, and many people even traumatic events over the course of their life, what is perceived as stressful is subjective (Fink, 2016). Therefore, interventions aiming to support and improve coping with stressful and traumatic life events should also follow a differential approach to stress appraisals. This refers not only to the design of interventions per se, but also to the conditions under which the interventions are applied. The purpose of this dissertation is to examine such conditions based on the results of three projects on psychological interventions to support coping with psychological distress due to an accident or the COVID-19 pandemic. For this purpose, the transactional stress theory (Lazarus & Folkman, 1984) is used as a framework to structure the analysis. More specifically, the results from all three projects and the six scientific articles resulting from them are discussed with regard the theory's elements. Afterwards, potential implications to be considered when designing an intervention are derived from this discussion. To conclude this dissertation, some limitations are discussed.

3.1 Discussion of the OptiFAB Project

Some references to the transactional stress theory (Lazarus & Folkman, 1984) can already be made based on the project's background and setting. First, the transactional nature of the stress experience is reflected in the collaborative care setting used in OptiFAB: stress is an interaction between the characteristics of the stressor and the individual, their abilities, and resources (Lazarus, 1999; Lazarus & Folkman, 1984, 1987). The project addressed this by first determining a screening to identify the greatest areas of stress (work-related, psychological, or both). Based on this, interventions targeting individual participants were implemented to promote their personal resources (resource activation). Second, some findings from previous

research on which the project is based can also be related to the transactional stress theory. This includes research suggesting that many injured patients experience a reduction in the health-related quality of life (Bryant et al., 2010; Lange et al., 2007), and that early psychological interventions can significantly reduce this impact (e.g., Giummarra et al., 2018). People who had an accident also form a highly heterogenous group since accidents and their consequences can differ greatly. Yet, not everyone who has had an accident develops psychological problems (Kühn, 2006). Thus, the fact that many, but not all, people develop psychological distress after an accident and that people who have had an accident represent a heterogeneous group illustrates the subjectivity of a stressor's appraisal. Furthermore, it also shows that despite the subjectivity of the appraisal, certain events, such as an accident, are difficult to cope with for many people. The references regarding previous research and the collaborative care approach show that it can be helpful to include both theory-based considerations as well as evidence-based findings when planning an intervention.

The subjectivity of the stressor is also reflected in the screening and tailored intervention provided within the OptiFAB project. The initial screening with the WHQ (Abegglen et al., 2017b) allowed the identification of individuals with elevated psychological or work-related distress, which indicated a tendency towards a complex rehabilitation process. Essentially, the screening assesses the primary appraisal of the transactional stress theory(Lazarus & Folkman, 1984): It determines for whom a psychological intervention is necessary at all. Based on the results of the screening, more cost-intensive interventions could be offered specifically to those people who need them. Moreover, individuals who do not perceive the accident and/or its aftermath as overwhelming or threatening, i.e., who do not exhibit distress, do not necessarily require psychological support (Biggs et al., 2017; Folkman et al., 1986; Lazarus & Folkman,

1984). Offering it anyway may cause unnecessary worries. Therefore, the initial screening is not only in line with the principle of stepped care and can save resources but may also prevent the pathologizing of an event that some people may not perceive as too stressful or traumatic.

Based on the results of the screening and diagnostic, the individual treatment was then developed. Through tailoring, the intervention not only took into account the subjective evaluation of the stressor through the primary appraisal, but also incorporated the secondary appraisal: Individual circumstances and challenges were considered in the face-to-face intervention. Despite the tailoring, the only significant intervention effect was a reduction of negative feelings in the intervention group ($d = 0.74$) compared to the control group ($d = 0.11$). Additionally, a significant improvement was observed in both groups concerning the health- and the family-related satisfaction over time. The significant improvement concerning health- and family-related satisfaction that was observed in both groups may have been caused by a natural adjustment process observed in some individuals. As time goes by, some people learn to cope with stressors and the stress and burden decrease (Biggs et al., 2017; Kendrick, Kelllezi, et al., 2017; Lange et al., 2007; Lazarus & Folkman, 1987). However, it is also possible that the changes in health and family-related satisfaction were brought about by the conventional case management, which all participants in both groups received as standard care. This would speak to the importance and efficacy of standard case management.

Although the findings regarding the reduction of negative feelings and the increase of health- and family-related satisfaction are important, the number of significant results was rather limited. One reason for this limited number of findings could be the low acceptability of the intervention. While the occupational counselling had an acceptance rate of 87.5%, the mental-health counselling had an acceptance rate of only 44%. Previous research has shown that

interventions targeting work-related issues often have a higher acceptance rate than psychosocial interventions (van der Klink et al., 2001). It is therefore important to consider not only the perception and evaluation of the stressor, but also that of the intervention. If the intervention itself is perceived as threatening, for example by being associated with the stigma that still surrounds mental health conditions and their treatment (Pedersen & Paves, 2014; Sickel et al., 2015), this can lead to negative appraisal and rejection of the intervention.

Although addressing the subjectivity of the stress experience by individualizing the intervention is important for the content of the intervention, it creates challenges for its scientific investigation. In OptiFAB, no treatment manual was provided for the intervention. This lack of standardization may limit the utility of the efficacy evaluation. If there is no specific instruction on how to proceed, there is less reliability in ascertaining which elements of the intervention led to which change or to any at all. As a result, the tailoring constitutes a black box (Hawkins et al., 2008; Kreuter & Wray, 2003). However, it can be argued that although no manual was provided, the same therapeutic approach was used throughout the intervention. Furthermore, the applied therapeutic approach is innately individualized, as each therapy is designed to be complementary to the needs of the respective patient (Grawe, 2004). Thus, although the intervention was not the same for everyone, it always followed the same principle and approach. Moreover, if the same thing were done in each case, it would no longer be tailoring. The trade-off between specificity and the tailoring of treatment can be compared to the trade-off between the subjectivity of the stress experience and the objective measurability of stress. For an intervention as well as for the assessment of stress, it is therefore important to determine which rules the assessment follows and how much room for individual differences is allowed within the framework of subjectivity or tailoring.

Another possible reason for the limited efficacy of the intervention is the high attrition rate over the course of the entire study. This might have limited the statistical power and made the valid detection of small effects harder. Several other studies on injury rehabilitation have also reported high dropout rates. To gain a deeper understanding of differential treatment effects, a moderator analysis was conducted (De Silva et al., 2009). For this purpose, different coping styles as well as dispositional optimism and dispositional pessimism were investigated as moderators of treatment efficacy. Dispositional optimism and the two coping styles emotion-oriented coping and social diversion were found to moderate the efficacy of the intervention with respect to three dimensions of well-being, namely life- and job satisfaction, and less negative feelings. These moderations show again that coping with stress is subjective and can affect the efficacy of an intervention. Therefore, it may be helpful to screen for coping strategies before an intervention and possibly to adapt the intervention accordingly. The finding that optimism was also a moderator of treatment efficacy is consistent with results of previous studies that have shown a similar influence (e.g., Reed, 2016; Solberg Nes & Segerstrom, 2006). The result of the moderator analysis further illustrates that a more differentiated understanding of the population under study can lead to more sophisticated interventions.

Some conclusions for further research were drawn from the projects' limitations. For example, a future intervention should be more extensive than the short coaching sessions that were used in OptiFAB. In addition, a different format, e.g., an IBI, should be considered. This could improve accessibility and increase acceptability, which in turn could lead to a lower dropout rate. Finally, a future intervention should also set in sooner after the accident so that the onset of (chronic) psychological distress can be prevented. All these recommendations were implemented in the SelFIT project.

3.2 Discussion of the SelFIT Project

Despite the implementation of all the evidence-based recommendations from the OptiFAB project, a recruitment period of one and a half years and intensive recruitment efforts, only 61 individuals registered for participation in the SelFIT intervention by signed informed consent. Thus, the target of 240 participants mentioned in the study protocol was missed by far. The discussion of possible reasons for the failed recruitment can both be related to the transactional stress model and provide valuable insights for the design of future interventions. Therefore, two possible reasons are discussed, and possible implications are deduced in light of transactional stress theory. The two possible reasons are: (1) injured persons did not feel addressed by the intervention, and (2) injured persons did not know about the intervention.

The first reason (accident victims did not feel addressed by the intervention) may be related to the perception of the stressor. According to the transactional stress theory, for an event to become a potential stressor, one must first notice a change (Biggs et al., 2017; Lazarus & Folkman, 1984). This also implies that a change can exist without being noticed and therefore does not become a potential stressor. Previous research has shown that after experiencing an accident, the focus lies primarily on physical symptoms and their treatment. Regarding psychological distress, emergency psychological care is now often available in cases of severe accidents. However, follow-up care is not ensured (Angenendt, 2021). For less severe accidents, where no paramedics or emergency psychologists are called to the scene, symptoms of psychological distress are often overlooked (Angenendt, 2014; Angenendt et al., 2016). SelFIT was not concerned with acute psychological reactions to an accident event, but with psychological distress developing after the acute phase. It is therefore possible that the people who SelFIT was aimed at did not notice psychological changes in themselves. Consequently,

those possible changes did not become a stressor, no need for psychological help arose and the SelFIT intervention did not appeal to them. Angenendt (2014) could show that persons who had an accident often only noticed psychological changes in themselves when they returned home or back to their everyday lives. Therefore, accident victims may attribute possible psychological changes occurring during this transition to the challenges of returning home or to work, or to getting used to new circumstances, and will thus not seek help. Particularly in the case of adjustment problems, which SelFIT was designed to address, symptoms are often only noticed once they have turned into a more severe burden (Bachem & Casey, 2018; Casey, 2018). Various studies have shown that subjectively perceived and objectively measured symptom severity and need for treatment often do not match (Mojtabai et al., 2011). However, many objectively distressed individuals believe their distress will go away on its own or that they can manage it on their own. These two attitudes are among the most commonly reported barriers to seeking psychological care (Coêlho et al., 2021; Henderson et al., 2013; Mojtabai et al., 2011; Sareen et al., 2007). A better understanding of such attitudinal barriers would be important to support the design of psychological interventions (Coêlho et al., 2021; Pedersen & Paves, 2014). Other frequently mentioned barriers to taking up psychological treatment are structural problems such as accessibility or financial difficulties (Mojtabai et al., 2011). Given the availability of free of charge support and the online format, these barriers should have been mitigated in the case of SelFIT.

However, another structural barrier may have been a problem: Injured persons did not know about the intervention. Regardless of whether an intervention appeals to people or not, if they do not know it exists, they cannot use it. That is why recruitment plays an important role (Axén et al., 2021; Kling et al., 2021). During the one-and-a-half-year recruitment period,

various recruiting methods were used. Some were selected on the basis of the digital format of the intervention. These include, for example, recruitment using Google Ads and Facebook Ads. Other channels were selected based on the target group of injured persons. These include requests to physiotherapists, rehabilitation centers, and hospitals to make accident patients aware of the study and/or to post flyers. Recruitment methods such as a mass email to students at the University of Bern and recruitment via social media and online forums were used, as this allowed many people to be reached with relatively little effort and resources. Finally, after obtaining consent, printed flyers were posted in public buildings or restaurants and the press was asked to report on the intervention. Although these are all strategies that have been effective and recommended in various studies (e.g., Axén et al., 2021; Kling et al., 2021; Morgan et al., 2013), they showed little effect in SelFIT or were turned down completely. Except for a reference to the study during a TV interview with the study' s principal investigator, requests to the press for a report on or brief mention of the study were not answered or were declined. Also, only one of 18 rehabilitation clinics agreed to help recruit potential participants. Furthermore, none of the 52 physical therapy practices contacted responded at all. To determine which of the recruitment strategies yielded how much, the question included in the first questionnaire about how participants learned about the study was evaluated. In the first questionnaire, participants were asked about the channel through which they found out about SelFIT. Of 53 people who answered the question, 17 people (32.07%) said they became aware of the intervention through a search on the Internet. 15 people (28.3%) were recruited through a mass email to students at the University of Bern and 9 people (16.98%) became aware of the intervention through advertising via flyers. 5 (9.43%) people stated that they had heard about the TV interview with the principal investigator themselves or through acquaintances and had thus learned about the intervention. 4

people (7.54%). were referred by a psychotherapist or rehabilitation clinic and the remaining 3 people (5.66%) were recruited via posts in online forums. This means, the three most successful recruitment strategies were (1) the personal research on the Internet, (2) sending a mass email to students at the University of Bern, and (3) recruitment by means of printed flyers. It should be noted here, however, that recruitment was very likely limited and influenced by the outbreak of the COVID-19 pandemic. For example, physical therapy practices had to close during prime recruitment periods, which puts the lack of response in a different light. Furthermore, requests for recruitment support from hospitals or rehabilitation clinics may also have been influenced by the COVID-19 pandemic. Nonetheless, the results on SelFIT's recruitment strategies can be discussed in light of findings from previous studies on recruitment in intervention studies. Axén et al. (2021) report that personal contact was a central aspect of successful recruitment in various studies they have conducted. The personal contact ranged from contact with professionals in clinics who helped with recruitment to decision makers in hospitals or politics. In those cases where we had personal contact, e.g., with the employees of the one participating rehabilitation clinic, we were promised support. However, the more difficult part was to establish the personal contact in the first place. Morgan et al.(2013) also report the importance of face-to-face contact, as participants and professionals can be better informed of the relevance of the topic and their own contribution. In terms of recruitment using online methods, both paid options (e.g., advertising on Google, Facebook and other social media) and unpaid options (e.g., posts on social media and online forums) were proven to be effective ways to of recruitment for intervention studies (Graham et al., 2008; Kling et al., 2021; Lane et al., 2015; Morgan et al., 2013; Musiat et al., 2016). Both paid and unpaid options tend to reach many people with relatively little effort. However, the personal contact is lost or limited. This is one of the reasons

why retention rates for online recruitment methods are often low (Lane et al., 2015). In addition, not all projects have the financial resources to pay for online recruitment methods.

Finally, the mode of delivery of the intervention and the target population should be considered. For example, online recruitment methods may be appropriate for IBI because they can easily be connected with the intervention (Kling et al., 2021; Lane et al., 2015; Musiat et al., 2016). Regarding the target population, for example, it should be taken into consideration whether they would feel addressed by online recruitment at all. In the case of SelFIT, it might have been more successful to approach more accident victims directly, as was done in the case of OptiFAB. One possibility to increase personal contact even in online recruitment methods would be to work with personal video messages from the researchers or the intervention team. This could be used not only for motivational messages to study participants, as Axén et al. (2021) report, but also as a personal touch to complement recruitment measures.

Due to the outbreak of the COVID-19 pandemic and the assumed increasing demand for psychological support associated with it, the ROCO intervention was developed, which is partly based on SelFIT. Findings from the ROCO intervention regarding what can be learned from it for the design of further interventions are described in the next chapter.

3.3 Discussion of the ROCO Project

In the first months of 2020, COVID-19 spread rapidly around the world and was declared a pandemic by the WHO (Benfante et al., 2020; Liang et al., 2020). It quickly became clear that the pandemic not only had an impact on physical health but also affected other areas of life (Gloster et al., 2020; Sanchez-Gomez et al., 2021). To address the large emerging need for psychological help (Gloster et al., 2020; Karekla et al., 2021; Luo et al., 2020), we developed the ROCO intervention to support psychological distress around the COVID-19 pandemic.

Regarding the transactional stress model, the primary target of the ROCO intervention were

people who were already experiencing. Additionally, with regard to the secondary appraisal,

persons who felt that their coping abilities and resources were limited, were addressed too.

ROCO was implemented as an internet-based self-help program with guidance on

demand for several reasons. First, the offer should not require any face-to-face contact to comply

with pandemic regulations concerning social distancing. Furthermore, access should be as simple

as possible. The intervention should also be easy to scale due to the assumed growing demand

for psychological support offers. To ensure the participants that, despite the interventions' being

implemented as a self-help program, a psychologist could be contacted if needed, the guidance

on demand format was employed. However, the offer was not widely used: Only three people

used the intervention's built-in chat function for a total of only 15 messages exchanged.

While psychological distress after an accident is often overlooked or not prioritized, the

opposite is more likely to be true for psychological distress surrounding the COVID-19

pandemic, which has also been referred to as a mental health pandemic (Gloster et al., 2020). In

other words, the pandemic and its consequences were and are highly salient, perceived as

relevant and appraised as stressors. Therefore, it is not surprising that the recruitment goal of at

least 80 participants was well achieved.

Regarding the efficacy of the intervention, no significant change could be observed in the

main outcome (depressive symptoms). However, when looking at within-group changes, there

was a reduction in depressive symptoms over time in both the experimental and control group.

This may indicate a trajectory called *recovery*: After a stressful experience, the level of distress

initially increases, before decreasing again over time and almost reaching the initial level

(Bonanno et al., 2012; Galatzer-Levy et al., 2018). Thus, the question arises whether it is

necessary to conduct an intervention to reduce psychological distress if the distress decreases on its own over time. However, it is not possible to know the course of the distress trajectories and whether recovery will occur at all beforehand. To be able to make more detailed statements about the trajectories of psychological distress surrounding the COVID-19 pandemic more research is needed. In any case, the ROCO intervention can serve not only in support of already existing psychological distress, but also for preventative purposes or to enhance potential recovery.

Among the secondary outcome measures, two significant changes were found: compared to the control group, participants in the experimental group showed an increase in resilience and emotion regulation skills from the baseline to the post-treatment assessment (three weeks after randomization) and the first follow-up (six weeks after randomization). These results seem reasonable given the content of ROCO: the intervention includes a module that focuses on promoting resilience, and emotions and emotion regulation are addressed several times.

Based on these findings, the question arises as to how many, and which outcomes should be assessed and in what form when designing an intervention. Which measure should be determined as the primary outcome measure and which or how many secondary outcomes should be assessed? In ROCO, the PHQ-9 questionnaire (Kroenke et al., 2001) assessing depressive symptoms was chosen as the primary outcome because stressful events often cause an increase in depressive symptoms (e.g., Kendler et al., 1998; Kessler, 1997; Sokratous et al., 2013), and the questionnaire is well-established and not too long. The seven additional outcome measures concerning aspects of psychological health that may be affected by the COVID-19 pandemic reflect the complexity and subjectivity of the experience of stress. Moreover, the COVID-19

pandemic was relatively new at the time the intervention began in May 2020, and only little data on mental health outcomes were available.

Therefore, it was feasible to collect rather many outcome measures in a situation, where hardly any evidence was available to inform the choice of potential outcome measures. Based on this, the design of a further intervention should consider (1) how much research is already available on the topic under investigation, (2) how much effort is required of the participants for each additional outcome measure, and (3) which criteria should be used to determine the choice of the primary outcome.

Assessing secondary outcomes has an additional advantage. They can be used to conduct secondary analyses to examine differential effects. As in OptiFAB, exploratory secondary analyses were conducted within the ROCO project because of the limited number of findings. More specifically, predictors of treatment efficacy were examined to find out more about which participant characteristics were associated with better treatment outcomes.

The results of these analyses suggest that younger participants in particular benefited from the ROCO intervention with regards to a reduction in depressive symptoms. In addition, a higher motivation to participate and better emotion regulation skills before the intervention were predictors of higher resilience scores after the intervention. Especially the finding that age is a predictor of treatment outcome for depressive symptoms highlights the importance of conducting secondary analyses. After all, this finding is not in line with the results of previous studies on internet-based self-help interventions for depression, in which age was not a predictor of treatment outcome. Through the secondary analysis, a differential result was found, which can and should be tested in further studies.

3.4 Implications for Future Interventions

Based on the discussed findings of the studies and aspects of the projects, several factors that may be considered in the design of future interventions can be derived.

Since all three projects dealt with psychological distress due to a traumatic event and thus, in a broader sense, psychological stress, the transactional stress theory was chosen to structure the findings. In this chapter, the findings are now summarized and integrated into a framework.

3.4.1 Stressor Related Considerations

For an event to become a potential stressor, a person must notice a change in the first place. This lack of perceived change is one potential explanation why SelFIT could not recruit enough participants. Therefore, it is important to clarify how the stressors that are to be addressed in the intervention are perceived. This goes hand in hand with clarifying whether the potential stressors are overlooked or downplayed by the target population itself, as well as by other stakeholders such as physicians, case managers or insurers, hospitals, etc.

Initial considerations about the choice of the interventions' mode of delivery can also be incorporated at the stressor level. In the case of ROCO, for example, it would have made little sense to design the intervention face-to-face, since the environmental requirements of the COVID-19 pandemic demanded social distancing and avoidance of personal contact as much as possible. Thus, an internet-based mode of delivery was chosen. In OptiFAB, on the other hand, an IBI would hardly have been suitable, as the intervention was to be embedded in the framework of (face-to-face) Suva case management.

3.4.2   *Primary Appraisal Related Considerations*

At the level of the primary appraisal, it should be clarified whether there is any need at all for offers of help or interventions. If potential participants do not feel the need for support, as it was the case with SelFIT, there may be no need for an intervention, or the planned intervention should be implemented differently. This should be linked to an assessment of the extent to which stressors are likely to be overlooked or mistakenly appraised as irrelevant. In the case of accidents, persons who have suffered an accident often assess psychological symptoms and distress as minor and self-manageable. Furthermore, professionals often miss the psychological consequences resulting from accidents (Angenendt, 2014). This can affect the intervention content and recruitment. For example, by employing recruitment strategies that involve personal contact, the needs of stakeholders can be addressed more individually. In addition, a personal contact recruitment strategy such as the one used in OptiFAB, where potential participants were approached by Suva case managers, can reach more people, in cases where potential stressors are often not perceived as such or are likely to be neglected. However, such collaborations, and recruitment with personal contact in general, tend to be rather time-consuming. Another way to identify potential symptoms or complaints is to conduct a screening, as was done in OptiFAB as well. By doing so, symptoms and distress can be made visible to both the affected person and the practitioner.

Regarding the primary appraisal, one should also consider how the subjectivity of the stress appraisal and the overall stress experience can be taken into account within the intervention and the project. This concerns, for example, the question of whether and what should be screened, and which outcome measures should be collected. These questions can be answered based on findings from previous research. However, especially when the stressor is

relatively new, such as the COVID-19 pandemic (ROCO), or when little relevant information is available, which was the case with adjustment problems after an accident (SelFIT), it may be worthwhile to collect additional measures in an exploratory manner. However, it must be considered how this affects the economics of the intervention and how high the resulting marginal benefit of an additional measure both for the participants and the project team is.

3.4.3   Secondary Appraisal Related Considerations

At the level of the secondary appraisal, various considerations should be addressed regarding resources, coping strategies and the focus of the intervention. Many psychological interventions to promote health focus on the secondary appraisal, i.e., the question of how the balance of resources and requirements can be strengthened and how suitable coping strategies can be promoted.

In this regard, it should be considered whether participants' existing resources can and should be taken into account. In the case of OptiFAB, for example, the tailoring of the intervention made it possible to address individual requirements and resources and to promote both purposefully. A screening conducted at the beginning can help to identify not only problem areas, but also resources.

Related to the secondary appraisal, there is also the question of whether and when it makes sense to facilitate either adaptive coping behaviors, or to promote a balance between demands and resources, or to address both. In some cases, the adjustment effort to a stressor may be strongly influenced by external demands and circumstances. For example, in the case of ROCO and the COVID-19 pandemic, it would have made little sense to promote resources that involved socializing with many people when the situation commanded social distancing instead.

If the focus of an intervention lies on prevention, the primary appraisal should also be targeted in addition to the elements of the secondary appraisal, since the goal is not only to deal with stress, but also to prevent an event from being appraised as stressful and demanding in the first place.

Furthermore, at the level of the secondary appraisal, it should be considered whether the stressor and the intervention are associated with stigmatization. In OptiFAB, for example, the occupational counselling had significantly higher acceptability rate than the mental health counselling, which may be due to the fact that psychological and therapeutic interventions are still stigmatized. This stigmatization may also in part account for SelFIT's low recruitment success.

3.4.4   *Coping and Learning Related Considerations*

With regard to coping, OptiFAB's secondary analysis showed that pre-existing and applied coping styles influenced the effectiveness of the intervention. Therefore, it can be concluded that in the context of an intervention to reduce psychological stress, it is reasonable to ascertain such pre-existing coping styles, for example by means of a screening, and to adapt the intervention accordingly.

Within the transactional stress model, the issue of attrition can be placed alongside the assessment of whether a chosen coping strategy was successful or not. Do participants drop out of an intervention when they feel they have received enough support, i.e., when the coping was successful? Or do participants drop out of an intervention if they feel the intervention is not helping enough in dealing with the stressor? In addition to a drop-out analysis, it may be useful to conduct secondary analyses on predictors or moderators to elicit differential treatment effects and further tailor the intervention to participants' needs.

At a meta-level, regarding learning and maturation, it can be concluded from this dissertation that it may be helpful to reflect on successful and failed elements of previous projects to draw conclusions for future interventions.

The factors summarized here, which were derived from the characteristics and results of the three projects OptiFAB, SelFIT and ROCO, are shown in Figure 2 below.

Figure 2

Aspects to consider for the design of an intervention aiming to reduce psychological distress due to a stressful life event based on the results of the OptiFAB, SelFIT and ROCO projects and guided by the transactional theory of stress (1984)
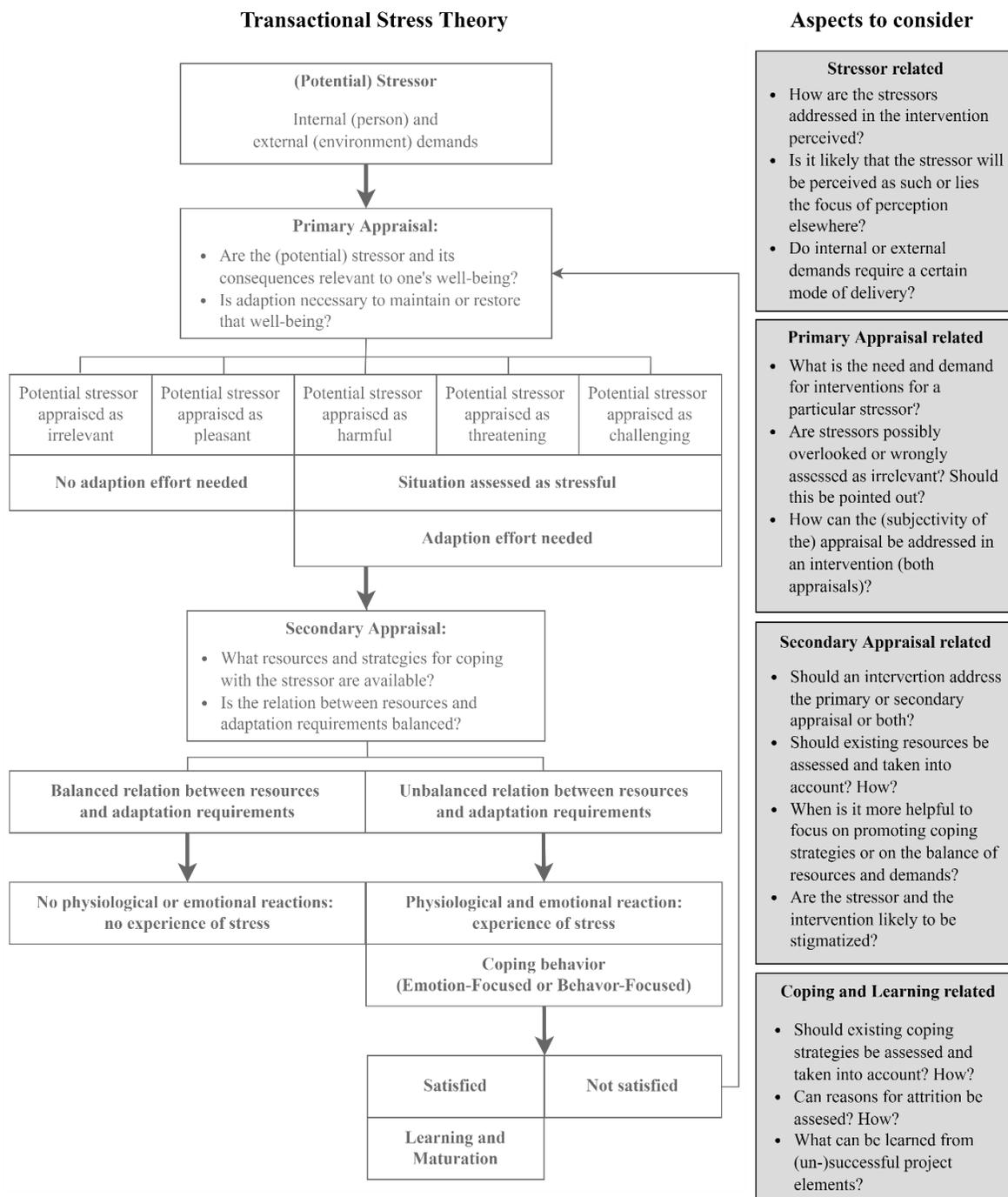
3.5 Limitations

There are some limitations to this dissertation that should be addressed. First, all recommendations and implications presented in this dissertation are based on three projects which have some common features and similarities. Hence, the evidence base is limited, which may affect the validity of the conclusions drawn from it.

The second limitation relates to the similarities of the three projects. All three projects are about supporting coping with traumatic events in a broader sense, and either accidents or COVID-19 in a narrower sense. Therefore, the results obtained from these projects may not be applicable to or suitable for other stressors or intervention topics. The same is true for the intervention mode. SelFIT and ROCO are both internet-based self-help interventions with guidance on demand. Therefore, it is possible that conclusions drawn from these interventions cannot be transferred to other intervention modes.

The third limitation is linked to the transactional stress theory, which served as a framework for structuring the discussion and derived implications. Although the theory is still much used and cited today, there are various further developments and newer theories and models. Most notably, there is the *Conservation of Resources Theory* (COR) by Stevan Hobfoll (1989, 2012). Within the transactional stress theory, resources are evaluated subjectively (Lazarus & Folkman, 1986). According to the COR theory, however, resources have both a subjective and an objective component, due to their instrumental and symbolic value (Hobfoll, 1989, 2012). It is through this subjective and objective value of resources that the COR theory implements a major criticism of transactional stress theory: Unlike Lazarus' and Folkman's model, it can be investigated more objectively (Knoll et al., 2017; Schwarzer & Luszczynska, 2012). The transactional stress theory can also be extended to include elements of other domains,

for example with respect to biological and neurological functions (McEwen & Gianaros, 2010). In this dissertation, however, only the basic version of the model by Lazarus and Folkman (1984)was considered.

Finally, there are various other theories and models, not only related to stress, which also deal with the planning of interventions or can be used for this purpose. Here, for example, the *Health Action Process Approach* (Schwarzer & Luszczynska, 2008), the *Theory of Planned Behavior* (Ajzen, 1985, 2002) and the *Transtheoretical Model of Change* (Prochaska & Diclemente, 1982) should be mentioned. These were not considered either but provide important information for the planning of future interventions, their content and structure.

Nevertheless, some information for the design of interventions aimed at reducing psychological distress due to a stressful event could be gained from the projects this dissertation is based on, and the transactional stress theory served as a framework to structure this. And so, the quote from T.S. Eliot that precedes this dissertation is applicable: the end of a project is often the beginning of something new. One need not always start from scratch but can let the end of one project inform the beginning of another. Thus, the design of a new project starts with the analysis and the end of the ones before.

4   References

Abegglen, S. (2017). *Einflüsse auf die Unfallverarbeitung und Massnahmen zur Unterstützung der Anpassung an leichte bis moderate unfallbedingte Verletzungen [Influences on accident processing and measures to support adjustment to mild to moderate accident-related injuries]*. https://boris.unibe.ch/111629/

Abegglen, S., Hoffmann-Richter, U., Schade, V., & Znoj, H. J. (2017a). Work and Health Questionnaire (WHQ): A Screening Tool for Identifying Injured Workers at Risk for a Complicated Rehabilitation. *Journal of Occupational Rehabilitation*, *27*(2), 268–283. https://doi.org/10.1007/s10926-016-9654-1

Abegglen, S., Hoffmann-Richter, U., Schade, V., & Znoj, H. J. (2017b). Work and Health Questionnaire (WHQ): A Screening Tool for Identifying Injured Workers at Risk for a Complicated Rehabilitation. *Journal of Occupational Rehabilitation*, *27*(2), 268–283. https://doi.org/10.1007/S10926-016-9654-1

Addis, D. R. (2020). Mental Time Travel? A Neurocognitive Model of Event Simulation. *Review of Philosophy and Psychology 2020 11:2*, *11*(2), 233–259. https://doi.org/10.1007/S13164-020-00470-0

Ajzen, I. (1985). From Intentions to Actions: A Theory of Planned Behavior. In *Action Control: From Cognition to Behavior* (pp. 11–39). Springer Verlag. https://doi.org/10.1007/978-3-642-69746-3_2

Ajzen, I. (2002). Perceived Behavioral Control, Self-Efficacy, Locus of Control, and the Theory of Planned Behavior1. *Journal of Applied Social Psychology*, *32*(4), 665–683. https://doi.org/https://doi.org/10.1111/j.1559-1816.2002.tb00236.x

Al-Alawi, M., McCall, R. K., Sultan, A., al Balushi, N., Al-Mahrouqi, T., al Ghailani, A., al

    Sabti, H., Al-Maniri, A., Panchatcharam, S. M., & al Sinawi, H. (2021). Efficacy of a

    six-week-long therapist-guided online therapy versus self-help internet-based therapy

    for COVID-19–induced anxiety and depression: Open-label, pragmatic, randomized

    controlled trial. *JMIR Mental Health*, *8*(2), e26683. https://doi.org/10.2196/26683

American Psychiatric Association. (2013). Trauma- and Stressor-Related Disorders. In

    Diagnostic and statistical manual of mental disorders, Fifth edition.

    https://doi.org/10.1176/appi.books.9780890425596.dsm07

Andersson, G. (2016). Internet-delivered psychological treatments. *Ann Rev Clin Psychol*,

    12, 157–179.

Andersson, G. (2018). Internet interventions: Past, present and future. *Internet*

    Interventions, *12*, 181–188. https://doi.org/10.1016/J.INVENT.2018.03.008

Andersson, G., Cuijpers, P., Carlbring, P., Riper, H., & Hedman, E. (2014). Guided

    Internet-based vs. face-to-face cognitive behavior therapy for psychiatric and somatic

    disorders: A systematic review and meta-analysis. *World Psychiatry*, *13*(3), 288–295.

    https://doi.org/10.1002/WPS.20151

Andrews, G., Cuijpers, P., Craske, M. G., McEvoy, P., & Titov, N. (2010). Computer

    therapy for the anxiety and depressive disorders is effective, acceptable and practical

    health care: A meta-analysis. In *PLoS ONE* (Vol. 5, Issue 10).

    https://doi.org/10.1371/journal.pone.0013196

Angenendt, J. (2014). Psychische Folgen von Unfällen und deren Versorgung [Interventions

    for mental health sequelae of accidents]. *Bundesgesundheitsblatt*, *57*, 666–672.

    https://doi.org/10.1007/s00103-014-1967-7

Angenendt, J. (2021). The broad spectrum of psychological sequelae of accidental trauma: Typical clinical pictures and stepped-care therapy. *Unfallchirurg*, *124*(1), 7–14. https://doi.org/10.1007/S00113-020-00935-Y

Angenendt, J., Drechsel-Schlund, C., Südkamp, N., & Berger, M. (2016). Notfallmedizin und Unfallchirurgie: Psychotraumatologie nach Unfällen [Emergency medicine and trauma surgery: Psychotraumatology after accidents]. *Deutsches Ärzteblatt*, *113*(40), A1752–A1754. https://www.aerzteblatt.de/archiv/182809/Notfallmedizin-und-Unfallchirurgie-Psychotraumatologie-nach-Unfaellen

Ashby, J. S., Rice, K. G., Kira, I. A., & Davari, J. (2021). The relationship of COVID-19 traumatic stress, cumulative trauma, and race to posttraumatic stress disorder symptoms. *Journal of Community Psychology*. https://doi.org/10.1002/JCOP.22762

Axén, I., Björk Brämberg, E., Galaasen Bakken, A., & Kwak, L. (2021). Recruiting in intervention studies: challenges and solutions. *BMJ Open*, *11*(1), e044702. https://doi.org/10.1136/BMJOPEN-2020-044702

Aymanns, P., & Filipp, S.-H. (2018). *Kritische Lebensereignisse und Lebenskrisen*. Kohlhammer Verlag.

Bachem, R., & Casey, P. (2018). Adjustment disorder: A diagnosis whose time has come. In *Journal of Affective Disorders* (Vol. 227, pp. 243–253). Elsevier B.V. https://doi.org/10.1016/j.jad.2017.10.034

Baumeister, H., Reichler, L., Munzinger, M., & Lin, J. (2014). The impact of guidance on Internet-based mental health interventions — A systematic review. *Internet Interventions*, *1*(4), 205–215. https://doi.org/10.1016/J.INVENT.2014.08.003

Benfante, A., di Tella, M., Romeo, A., & Castelli, L. (2020). Traumatic Stress in Healthcare

    Workers During COVID-19 Pandemic: A Review of the Immediate Impact. *Frontiers*

    in Psychology, *11*, 2816. https://doi.org/10.3389/FPSYG.2020.569935

Bengel, J., Becker-Nehring, K., & Hillebrecht, J. (2019). Psychologische

    Frühinterventionen. *Traumafolgestörungen*, 189–216. https://doi.org/10.1007/978-3-

    662-58470-5_10

Bengel, J., & Hubert, S. (2010). *Anpassungsstörung und Akute Belastungsreaktion*

    [Adjustment disorder and acute stress response]. Hogrefe Verlag GmbH.

Benjet, C., Bromet, E., Karam, E. G., Kessler, R. C., McLaughlin, K. A., Ruscio, A. M.,

    Shahly, V., Stein, D. J., Petukhova, M., Hill, E., Alonso, J., Atwoli, L., Bunting, B.,

    Bruffaerts, R., Caldas-de-Almeida, J. M., de Girolamo, G., Florescu, S., Gureje, O.,

    Huang, Y., … Koenen, K. C. (2016). The epidemiology of traumatic event exposure

    worldwide: results from the World Mental Health Survey Consortium. *Psychological*

    Medicine, *46*(2), 327. https://doi.org/10.1017/S0033291715001981

Berger, T. (2015). *Internetbasierte Interventionen bei psychischen Störungen*. Hogrefe.

Berger, T., Bur, O., & Krieger, T. (2019). Internet-Based Psychotherapeutic Interventions.

    PPmP Psychotherapie Psychosomatik Medizinische Psychologie, *69*(9–10), 413–426.

    https://doi.org/10.1055/A-0963-9055/ID/R9639055-0020

Berger, T., Bur, O., & Krieger, T. (2020). Internet-Interventionen in der Psychotherapie.

    Fortschritte Der Neurologie Psychiatrie, *88*(10), 677–689. https://doi.org/10.1055/A-

    1165-7496/ID/JR7496-0020

Berger, T., & Caspar, F. (2011). Internetbasierte Psychotherapien [Internet-based psychotherapies]. *Psychiatrie Und Psychotherapie Up2date*, *5*, 29–43. https://doi.org/10.1055/s-0030-1265934

Berger, T., Caspar, F., Richardson, R., Kneubühler, B., Sutter, D., & Andersson, G. (2011). Internet-based treatment of social phobia: A randomized controlled trial comparing unguided with two types of guided self-help. *Behaviour Research and Therapy*, *49*(3), 158–169. https://doi.org/10.1016/J.BRAT.2010.12.007

Berger, T., & Krieger, T. (2018). Internet Interventionen: Ein Überblick. *Psychotherapie Im Dialog*, *4*, 18–23.

Berntsen, D., & Rubin, D. C. (2015). Pretraumatic Stress Reactions in Soldiers Deployed to Afghanistan. *Clinical Psychological Science : A Journal of the Association for Psychological Science*, *3*(5), 663–674. https://doi.org/10.1177/2167702614551766

Bienertova-Vasku, J., Lenart, P., & Scheringer, M. (2020). Eustress and Distress: Neither Good Nor Bad, but Rather the Same? *BioEssays*, *42*(7), 1900238. https://doi.org/https://doi.org/10.1002/bies.201900238

Biggs, A., Brough, P., & Drummond, S. (2017). Lazarus and Folkman's Psychological Stress and Coping Theory. In C. L. Cooper & J. Campbell Quick (Eds.), *The Handbook of Stress and Health. A Guide to Research aqnd Practice* (pp. 351–364). John Wiley & Sons, Ltd. https://doi.org/10.1002/9781118993811

Boehnke, K. F., McAfee, J., Ackerman, J. M., & Kruger, D. J. (2021). Medication and substance use increases among people using cannabis medically during the COVID-19 pandemic. *International Journal of Drug Policy*, *92*, 103053. https://doi.org/10.1016/J.DRUGPO.2020.103053

Bonanno, G. A., Kennedy, P., Galatzer-Levy, I. R., Lude, P., & Elfström, M. L. (2012). Trajectories of resilience, depression, and anxiety following spinal cord injury. *Rehabilitation Psychology*, *57*(3), 236–247. https://doi.org/10.1037/a0029256

Bradley, E. H., Curry, L. A., Taylor, L. A., Pallas, S. W., Talbert-Slagle, K., Yuan, C., Fox, A., Minhas, D., Ciccone, D. K., Berg, D., & Pérez-Escamilla, R. (2012). A model for scale up of family health innovations in low-income and middle-income settings: A mixed methods study. *BMJ Open*, *2*(4). https://doi.org/10.1136/BMJOPEN-2012-000987

Bridgland, V. M. E., Moeck, E. K., Green, D. M., Swain, T. L., Nayda, D. M., Matson, L. A., Hutchison, N. P., & Takarangi, M. K. T. (2021). Why the COVID-19 pandemic is a traumatic stressor. *PLoS ONE*, *16*(1). https://doi.org/10.1371/JOURNAL.PONE.0240146

Brooks, S. K., Webster, R. K., Smith, L. E., Woodland, L., Wessely, S., Greenberg, N., & Rubin, G. J. (2020). The psychological impact of quarantine and how to reduce it: rapid review of the evidence. *The Lancet*, *395*(10227), 912–920. https://doi.org/10.1016/S0140-6736(20)30460-8

Bryant, R. A., O'Donnell, M. L., Creamer, M., McFarlane, A. C., Clark, C. R., & Silove, D. (2010). The psychiatric sequelae of traumatic injury. *American Journal of Psychiatry*, *167*(3), 312–320. https://doi.org/10.1176/APPI.AJP.2009.09050617

Buckner, R. L., & Carroll, D. C. (2007). Self-projection and the brain. *Trends in Cognitive Sciences*, *11*(2), 49–57. https://doi.org/10.1016/J.TICS.2006.11.004

Bundesamt für Gesundheit BAG [Federal Office of Public Health FOPH]. (2021). *Coronavirus: So schützen wir uns*.

https://www.bag.admin.ch/bag/de/home/krankheiten/ausbrueche-epidemien-pandemien/aktuelle-ausbrueche-epidemien/novel-cov/so-schuetzen-wir-uns.html#

Bundesamt für Statistik. (2021). *Die Bevölkerung der Schweiz im Jahr 2020*. https://www.bfs.admin.ch/bfs/de/home/statistiken/bevoelkerung.assetdetail.19964430.html

Casey, P. (2018). *Adjustment Disorder - from controversy to clinical practice* (Fist editi). Oxford University Press.

Coêlho, B. M., Santana, G. L., Viana, M. C., Wang, Y.-P., & Andrade, L. H. (2021). "I don't need any treatment" - barriers to mental health treatment in the general population of a megacity. *Revista Brasileira de Psiquiatria (Sao Paulo, Brazil : 1999)*, *43*(6), 590–598. https://doi.org/10.1590/1516-4446-2020-1448

Cohen, S., Gianaros, P. J., & Manuck, S. B. (2016). A Stage Model of Stress and Disease. *Perspectives on Psychological Science*, *11*(4), 456–463. https://doi.org/10.1177/1745691616646305

Cohen, S., Janicki-Deverts, D., & Miller, G. E. (2007). Psychological Stress and Disease. *JAMA*, *298*(14), 1685–1687. https://doi.org/10.1001/JAMA.298.14.1685

Cooke, J. E., Eirich, R., Racine, N., & Madigan, S. (2020). Prevalence of posttraumatic and general psychological stress during COVID-19: A rapid review and meta-analysis. *Psychiatry Research*, *292*, 113347. https://doi.org/10.1016/J.PSYCHRES.2020.113347

Cooper, C. L., & Campbell Quick, J. (Eds.). (2017). *The Handbook of Stress and Health. A Guide to Research and Practice*. John Wiley & Sons, Ltd. https://doi.org/10.1002/9781118993811

Cooper, C. L., & Dewe, P. (2004). Stress: A Brief History. In *Stress: A Brief History*. Blackwell Publishing. https://doi.org/10.1002/9780470774755

cpmo. (2015). *Centrum für Personal Management und Organisationsgestaltung*. https://cpmo.ch/

de Munter, L., Polinder, S., Haagsma, J. A., Kruithof, N., van de Ree, C. L. P., Steyerberg, E. W., & de Jongh, M. (2020). Prevalence and Prognostic Factors for Psychological Distress After Trauma. *Archives of Physical Medicine and Rehabilitation*, *101*(5), 877–884. https://doi.org/10.1016/J.APMR.2019.10.196

de Quervain, D., Aerni, A., Amini, E., Bentz, D., Coynel, D., Gerhards, C., Freytag, V., Papassotiropoulos, A., Schicktanz, N., Schlitt, T., Zimmer, A., & Zuber, P. (2021). The Swiss Corona Stress Study: November 2021. *OSF Preprints*. https://doi.org/https://doi.org/10.31219/osf.io/x6zu7

De Silva, M., MacLachlan, M., Devane, D., Desmond, D., Gallagher, P., Schnyder, U., Brennan, M., & Patel, V. (2009). Psychosocial interventions for the prevention of disability following traumatic physical injury. In *Cochrane Database of Systematic Reviews* (Vol. 2009, Issue 4). John Wiley and Sons Ltd. https://doi.org/10.1002/14651858.CD006422.pub3

Didriksen, M., Werge, T., Nissen, J., Schwinn, M., Sørensen, E., Nielsen, K. R., Bruun, M. T., Banasik, K., Hansen, T. F., Erikstrup, C., Ostrowski, S. R., Jennum, P. J., Hjalgrim, H., Ullum, H., & Pedersen, O. B. (2021). Impact of COVID-19 Pandemic on Sleep Quality, Stress Level and Health-Related Quality of Life-A Large Prospective Cohort Study on Adult Danes. *International Journal of Environmental Research and Public Health*, *18*(14), 7610. https://doi.org/10.3390/ijerph18147610

Ebert, D. D., Berking, M., Cuijpers, P., Lehr, D., Pörtner, M., & Baumeister, H. (2015). Increasing the acceptance of internet-based mental health interventions in primary care patients with depressive symptoms. A randomized controlled trial. *Journal of Affective Disorders*, *176*, 9–17. https://doi.org/10.1016/J.JAD.2015.01.056

Ebert, D. D., Heber, E., Berking, M., Riper, H., Cuijpers, P., Funk, B., & Lehr, D. (2016a). Self-guided internet-based and mobile-based stress management for employees: results of a randomised controlled trial. *Occupational and Environmental Medicine*, *73*(5), 315–323. https://doi.org/10.1136/OEMED-2015-103269

Ebert, D. D., Heber, E., Berking, M., Riper, H., Cuijpers, P., Funk, B., & Lehr, D. (2016b). Self-guided internet-based and mobile-based stress management for employees: Results of a randomised controlled trial. *Occupational and Environmental Medicine*, *73*(5), 315–323. https://doi.org/10.1136/oemed-2015-103269

Ebert, D. D., Lehr, D., Boss, L., Riper, H., Cuijpers, P., Andersson, G., Thiart, H., Heber, E., & Berking, M. (2014). Efficacy of an internet-based problem-solving training for teachers: results of a randomized controlled trial. *Scandinavian Journal of Work, Environment & Health*, *40*(6), 582–596. https://doi.org/10.5271/SJWEH.3449

Egli, S. (2018). *Unfall oder Krankheit? Das ist hier die Frage! [Accident or illness? That is the question!]*. https://www.suva.ch/de-ch/news/2018/unfall-oder-krankheit

Elmiger, D. (2015). Das Schadenmanagement der Suva [Claim managementnt of Suva]. *5. GMTTB Jahrestagung*, 1–17. https://docplayer.org/19741096-Das-schadenmanagement-der-suva-daniel-elmiger-suva-leiter-ausbildung-schadenmanagement-care-5-gmttb-jahrestagung-konstanz-16-4.html

Erbe, D., Psych, D., Eichert, H. C., Riper, H., & Ebert, D. D. (2017). Blending Face-to-Face and Internet-Based Interventions for the Treatment of Mental Disorders in Adults: Systematic Review. *J Med Internet Res 2017;19(9):E306 Https://Www.Jmir.Org/2017/9/E306*, *19*(9), e6588. https://doi.org/10.2196/JMIR.6588

Ettman, C. K., Abdalla, S. M., Cohen, G. H., Sampson, L., Vivier, P. M., & Galea, S. (2020). Prevalence of Depression Symptoms in US Adults Before and During the COVID-19 Pandemic. *JAMA Network Open*, *3*(9), e2019686–e2019686. https://doi.org/10.1001/JAMANETWORKOPEN.2020.19686

Faltermaier, T. (2017). *Gesundheitspsychologie [Health psychology]* (Zweite, üb). Kohlhammer Verlag.

Fink, G. (2016). Stress, Definitions, Mechanisms, and Effects Outlined: Lessons from Anxiety. In G. Fink (Ed.), *Stress: Concepts, Cognition, Emotion, and Behavior. Handbook of Stress Series Volume 1* (pp. 3–11). Academic Press Elsevier. https://doi.org/https://doi.org/10.1016/B978-0-12-800951-2.00001-7

Fiorillo, A., & Gorwood, P. (2020). The consequences of the COVID-19 pandemic on mental health and implications for clinical practice. *European Psychiatry*, *63*(1). https://doi.org/10.1192/J.EURPSY.2020.35

Folkman, S., Lazarus, R. S., Gruen, R. J., & DeLongis, A. (1986). Appraisal, Coping, Health Status, and Psychological Symptoms. *Journal of Personality and Social Psychology*, *50*(3), 571–579. https://doi.org/10.1037/0022-3514.50.3.571

Frommberger, U., Angenendt, J., & Berger, M. (2014). Post-Traumatic Stress Disorder—a Diagnostic and Therapeutic Challenge. *Deutsches Ärzteblatt International*, *111*(5), 59. https://doi.org/10.3238/ARZTEBL.2014.0059

Gagliardi, A. R. (2011). Tailoring interventions: Examining the evidence and identifying gaps. *Journal of Continuing Education in the Health Professions*, *31*(4), 276–282. https://doi.org/10.1002/CHP.20141

Galatzer-Levy, I. R., Huang, S. H., & Bonanno, G. A. (2018). Trajectories of resilience and dysfunction following potential trauma: A review and statistical evaluation. *Clinical Psychology Review*, *63*, 41–55. https://doi.org/10.1016/J.CPR.2018.05.008

Giummarra, M. J., Lennox, A., Dali, G., Costa, B., & Gabbe, B. J. (2018). Early psychological interventions for posttraumatic stress, depression and anxiety after traumatic injury: A systematic review and meta-analysis. In *Clinical Psychology Review* (Vol. 62, pp. 11–36). Elsevier Inc. https://doi.org/10.1016/j.cpr.2018.05.001

Gloster, A. T., Lamnisos, D., Lubenko, J., Presti, G., Squatrito, V., Constantinou, M., Nicolaou, C., Papacostas, S., Aydın, G., Chong, Y. Y., Chien, W. T., Cheng, H. Y., Ruiz, F. J., Garcia-Martin, M. B., Obando-Posada, D. P., Segura-Vargas, M. A., Vasiliou, V. S., McHugh, L., Höfer, S., … Karekla, M. (2020). Impact of COVID-19 pandemic on mental health: An international study. *PLoS ONE*, *15*(12), e0244809. https://doi.org/https://doi.org/10.1371/journal.pone.0244809

Gobbi, S., Płomecka, M. B., Ashraf, Z., Radziński, P., Neckels, R., Lazzeri, S., Dedić, A., Bakalović, A., Hrustić, L., Skórko, B., Es haghi, S., Almazidou, K., Rodríguez-Pino, L., Alp, A. B., Jabeen, H., Waller, V., Shibli, D., Behnam, M. A., Arshad, A. H., … Jawaid, A. (2020). Worsening of Preexisting Psychiatric Conditions During the COVID-19 Pandemic. *Frontiers in Psychiatry*, *11*, 1407. https://doi.org/10.3389/FPSYT.2020.581426

Goutaudier, N., Bertoli, C., Séjourné, N., & Chabrol, H. (2018). Childbirth as a forthcoming traumatic event: pretraumatic stress disorder during pregnancy and its psychological correlates. *Https://Doi.Org/10.1080/02646838.2018.1504284*, *37*(1), 44–55. https://doi.org/10.1080/02646838.2018.1504284

Graf, A. S., Long, D. M., & Patrick, J. H. (2017). Successful Aging Across Adulthood: Hassles, Uplifts, and Self-Assessed Health in Daily Context. *Journal of Adult Development*, *24*(3), 216–225. https://doi.org/10.1007/S10804-017-9260-2

Graham, A. L., Milner, P., Saul, J. E., & Pfaff, L. (2008). Online advertising as a public health and recruitment tool: Comparison of different media campaigns to increase demand for smoking cessation interventions. *Journal of Medical Internet Research*, *10*(5). https://doi.org/10.2196/JMIR.1001

Grawe, K. (2004). *Psychological therapy*. Hogrefe & Huber Publishers.

Halder, S. (2020). COVID-19: psychological impact and psychotherapeutic intervention. *EC Psychol Psychiatry*, *9*, 32–35.

Hawkins, R. P., Kreuter, M., Resnicow, K., Fishbein, M., & Dijkstra, A. (2008). Understanding tailoring in communicating about health. *Health Education Research*, *23*(3), 454–466. https://doi.org/10.1093/HER/CYN004

Henderson, C., Evans-Lacko, S., & Thornicroft, G. (2013). Mental Illness Stigma, Help Seeking, and Public Health Programs. *American Journal of Public Health*, *103*(5), 777. https://doi.org/10.2105/AJPH.2012.301056

Hobfoll, S. E. (1989). Conservation of resources. A new attempt at conceptualizing stress. *The American Psychologist*, *44*(3), 513–524. https://doi.org/10.1037//0003-066X.44.3.513

Hobfoll, S. E. (2012). Conservation of Resources Theory: Its Implication for Stress, Health, and Resilience. In S. Folkman (Ed.), *The Oxford Handbook of Stress, Health, and Coping* (pp. 127–147). Oxford University Press. https://doi.org/10.1093/OXFORDHB/9780195375343.013.0007

Holmes, E. A., O'Connor, R. C., Perry, V. H., Tracey, I., Wessely, S., Arseneault, L., Ballard, C., Christensen, H., Cohen Silver, R., Everall, I., Ford, T., John, A., Kabir, T., King, K., Madan, I., Michie, S., Przybylski, A. K., Shafran, R., Sweeney, A., … Bullmore, E. (2020). Multidisciplinary research priorities for the COVID-19 pandemic: a call for action for mental health science. *The Lancet Psychiatry*, *7*(6), 547–560. https://doi.org/10.1016/S2215-0366(20)30168-1

Horesh, D., & Brown, A. D. (2020). Covid-19 response: Traumatic stress in the age of Covid-19: A call to close critical gaps and adapt to new realities. *Psychological Trauma: Theory, Research, Practice, and Policy*, *12*(4), 331–335. https://doi.org/10.1037/TRA0000592

Kanner, A. D., Coyne, J. C., Schaefer, C., & Lazarus, R. S. (1981). Comparison of two modes of stress measurement: Daily hassles and uplifts versus major life events. *Journal of Behavioral Medicine 1981 4:1*, *4*(1), 1–39. https://doi.org/10.1007/BF00844845

Kapfhammer, H. P. (2014). Trauma and stressor-related disorders: diagnostic conceptualization in DSM-5. *Der Nervenarzt*, *85*(5), 553–563. https://doi.org/10.1007/S00115-013-3988-0

Karekla, M., Höfer, S., Plantade-Gipch, A., Neto, D. D., Schjødt, B., David, D., Schütz, C., Elepftheriou, A., Pappová, P. K., Lowet, K., McCracken, L., Sargautytė, R.,

Scharnhorst, J., & Hart, J. (2021). The Role of Psychologists in Healthcare During the COVID-19 Pandemic. *European Journal of Psychology Open*, *80*, 5–17. https://doi.org/https://doi.org/10.1024/2673-8627/a000003

Kellezi, B., Coupland, C., Morriss, R., Beckett, K., Joseph, S., Barnes, J., Christie, N., Sleney, J., & Kendrick, D. (2017). The impact of psychological factors on recovery from injury: a multicentre cohort study. *Social Psychiatry and Psychiatric Epidemiology*, *52*(7), 855–866. https://doi.org/10.1007/s00127-016-1299-z

Kendler, K. S., Karkowski, L. M., & Prescott, C. A. (1998). Stressful life events and major depression: risk period, long-term contextual threat and diagnostic specificity. *J Nerv Ment Dis*, *186*(11), 661–669. https://doi.org/10.1097/00005053-199811000-00001

Kendrick, D., Coupland, C., Whitehead, J., Joseph, S., Morriss, R., Dhiman, P., Kellezi, B., Beckett, K., Christie, N., Sleney, J., & Barnes, J. (2017). Psychological morbidity and return to work after injury: multicentre cohort study. *The British Journal of General Practice*, *67*(661), e555. https://doi.org/10.3399/BJGP17X691673

Kendrick, D., Kelllezi, B., Coupland, C., Maula, A., Beckett, K., Morriss, R., Joseph, S., Barnes, J., Sleney, J., & Christie, N. (2017). Psychological morbidity and health-related quality of life after injury: multicentre cohort study. *Quality of Life Research*, *26*(5), 1233–1250. https://doi.org/10.1007/s11136-016-1439-7

Kessler, R. C. (1997). The effects of stressful life events on depression. *Annu Rev Psychol*, *48*, 191–214. https://doi.org/10.1146/annurev.psych.48.1.191

Kessler, R. C., Aguilar-Gaxiola, S., Alonso, J., Benjet, C., Bromet, E. J., Cardoso, G., Degenhardt, L., de Girolamo, G., Dinolova, R. v., Ferry, F., Florescu, S., Gureje, O., Haro, J. M., Huang, Y., Karam, E. G., Kawakami, N., Lee, S., Lepine, J. P., Levinson,

D., … Koenen, K. C. (2017). Trauma and PTSD in the WHO World Mental Health

Surveys. *European Journal of Psychotraumatology*, *8*, 5.

https://doi.org/10.1080/20008198.2017.1353383

Kira, I. A., Shuwiekh, H. A. M., Rice, K. G., Ashby, J. S., Elwakeel, S. A., Sous, M. S. F.,

Alhuwailah, A., Baali, S. B. A., Azdaou, C., Oliemat, E. M., & Jamil, H. J. (2020).

Measuring COVID-19 as Traumatic Stress: Initial Psychometrics and Validation.

Https://Doi.Org/10.1080/15325024.2020.1790160, *26*(3), 1–18.

https://doi.org/10.1080/15325024.2020.1790160

Kling, J., Nordgreen, T., Kvalem, I. L., Williamson, H., & Feragen, K. B. (2021).

Recruiting difficult-to-engage groups to online psychosocial interventions:

Experiences from an RCT study targeting adolescents with a visible difference.

Contemporary Clinical Trials Communications, *24*, 100869.

https://doi.org/10.1016/J.CONCTC.2021.100869

Knipscheer, J., Sleijpen, M., Frank, L., de Graaf, R., Kleber, R., ten Have, M., & Dückers,

M. (2020). Prevalence of Potentially Traumatic Events, Other Life Events and

Subsequent Reactions Indicative for Posttraumatic Stress Disorder in the Netherlands:

A General Population Study Based on the Trauma Screening Questionnaire.

International Journal of Environmental Research and Public Health 2020, Vol. 17,

Page 1725, *17*(5), 1725. https://doi.org/10.3390/IJERPH17051725

Knoll, N., Scholz, U., & Rieckmann, N. (2017). *Einführung Gesundheitspsychologie*

[Introduction Health Psychology]. Ernst Reinhardt Verlag.

Koolhaas, J. M., Bartolomucci, A., Buwalda, B., de Boer, S. F., Flügge, G., Korte, S. M.,

Meerlo, P., Murison, R., Olivier, B., Palanza, P., Richter-Levin, G., Sgoifo, A.,

Steimer, T., Stiedl, O., van Dijk, G., Wöhr, M., & Fuchs, E. (2011). Stress revisited: A critical evaluation of the stress concept. *Neuroscience & Biobehavioral Reviews*, *35*(5), 1291–1301. https://doi.org/10.1016/J.NEUBIOREV.2011.02.003

Koordinationsgruppe für die Statistik der Unfallversorgung UVG. (2021). *Unfallstatistik UVG 2020*. https://www.suva.ch/de-CH/material/Dokumentationen/unfallstatistik-uvg-ssuv-2020

Kraemer, H. C., Wilson, G. T., Fairburn, C. G., & Agras, W. S. (2002). Mediators and Moderators of Treatment Effects in Randomized Clinical Trials. *Archives of General Psychiatry*, *59*(10), 877–883. https://doi.org/10.1001/ARCHPSYC.59.10.877

Kreuter, M. W., & Wray, R. J. (2003). Tailored and Targeted Health Communication: Strategies for Enhancing Information Relevance. *American Journal of Health Behavior*, *27*(SUPPL. 3). https://doi.org/10.5993/AJHB.27.1.S3.6

Kroenke, K., Spitzer, R. L., & Williams, J. B. W. (2001). The PHQ-9: Validity of a brief depression severity measure. *Journal of General Internal Medicine*, *16*(9), 606–613. https://doi.org/10.1046/j.1525-1497.2001.016009606.x

Kühn, M. (2006). *Die psychischen Folgen von schweren Unfällen und ihre Prädiktoren*. https://doi.org/https://doi.org/10.5167/uzh-165153

Lane, T. S., Armin, J., & Gordon, J. S. (2015). Online Recruitment Methods for Web-Based and Mobile Health Studies: A Review of the Literature. *J Med Internet Res 2015;17(7):E183 Https://Www.Jmir.Org/2015/7/E183*, *17*(7), e4359. https://doi.org/10.2196/JMIR.4359

Lange, C., Burgmer, M., Braunheim, M., & Heuft, G. (2007). Prospective analysis of factors associated with work reentry in patients with accident-related injuries. *Journal*

of Occupational Rehabilitation, *17*(1), 1–10. https://doi.org/10.1007/S10926-006-9039-Y

Larsson, G., Berglund, A. K., & Ohlsson, A. (2016). Daily hassles, their antecedents and outcomes among professional first responders: A systematic literature review. *Scandinavian Journal of Psychology*, *57*(4), 359–367. https://doi.org/10.1111/SJOP.12303

Lazarus, R. S. (1984). Puzzles in the study of daily hassles. *Journal of Behavioral Medicine*, *7*, 375–389. https://doi.org/https://doi.org/10.1007/BF00845271

Lazarus, R. S. (1999). *Stress and emotion: a new synthesis*. Springer Publishing Company.

Lazarus, R. S. (2006). *Stress and Emotion: A New Synthesis*. Springer.

Lazarus, R. S., & Folkman, S. (1984). *Stress, Appraisal, and Coping*. Springer.

Lazarus, R. S., & Folkman, S. (1986). Cognitive Theories of Stress and the Issue of Circularity. In M. H. Appley & R. Trumbull (Eds.), *Dynamics of Stress. The Plenum Series on Stress and Coping* (pp. 63–80). Springer. https://doi.org/https://doi.org/10.1007/978-1-4684-5122-1_4

Lazarus, R. S., & Folkman, S. (1987). Transactional theory and research on emotions and coping. *European Journal of Personality*, *1*(3), 141–169. https://doi.org/10.1002/PER.2410010304

Liang, L., Gao, T., Ren, H., Cao, R., Qin, Z., Hu, Y., Li, C., & Mei, S. (2020). Post-traumatic stress disorder and psychological distress in Chinese youths following the COVID-19 emergency. *Journal of Health Psychology*, *25*(9), 1164–1175. https://doi.org/10.1177/1359105320937057

Luo, M., Guo, L., Yu, M., & Wang, H. (2020). The psychological and mental impact of

coronavirus disease 2019 (COVID-19) on medical staff and general public – A

systematic review and meta-analysis. *Psychiatry Research*, *291*, 113190.

https://doi.org/10.1016/J.PSYCHRES.2020.113190

Maercker, A. (Ed.). (2019). *Traumafolgestörungen. Fünfte Auflage*. Springer.

https://doi.org/https://doi.org/10.1007/978-3-662-58470-5

Matthews, L. R., & Chinnery, D. (2005). Prediction of work functioning following

accidental injury: The contribution of PTSD symptom severity and other established

risk factors. *International Journal of Psychology*, *40*(5), 339–348.

https://doi.org/10.1080/00207590444000320

Matthews, L. R., Harris, L. M., & Cumming, S. (2009). Trauma-related appraisals and

coping styles of injured adults with and without symptoms of PTSD and their

relationship to work potential. *Https://Doi.Org/10.1080/09638280802639012*, *31*(19),

1577–1583. https://doi.org/10.1080/09638280802639012

McEwen, B. S., & Gianaros, P. J. (2010). Central role of the brain in stress and adaptation:

Links to socioeconomic status, health, and disease. *Annals of the New York Academy of

Sciences*, *1186*, 190–222. https://doi.org/10.1111/j.1749-6632.2009.05331.x

Mira, A., Soler, C., Alda, M., Baños, R., Castilla, D., Castro, A., García-Campayo, J.,

García-Palacios, A., Gili, M., Hurtado, M., Mayoral, F., Montero-Marín, J., & Botella,

C. (2019). Exploring the relationship between the acceptability of an internet-based

intervention for depression in primary care and clinical outcomes: Secondary analysis

of a randomized controlled trial. *Frontiers in Psychiatry*, *10*(MAY), 325.

https://doi.org/10.3389/FPSYT.2019.00325

Mojtabai, R., Olfson, M., Sampson, N. A., Jin, R., Druss, B., Wang, P. S., Wells, K. B.,

    Pincus, H. A., & Kessler, R. C. (2011). Barriers to Mental Health Treatment: Results

    from the National Comorbidity Survey Replication (NCS-R). *Psychological Medicine*,

    41(8), 1751. https://doi.org/10.1017/S0033291710002291

Morgan, A. J., Jorm, A. F., & Mackinnon, A. J. (2013). Internet-Based Recruitment to a

    Depression Prevention Intervention: Lessons From the Mood Memos Study. *Journal of*

    Medical Internet Research, *15*(2). https://doi.org/10.2196/JMIR.2262

Murphy, L., Markey, K., O' Donnell, C., Moloney, M., & Doody, O. (2021). The impact of

    the COVID-19 pandemic and its related restrictions on people with pre-existent mental

    health conditions: A scoping review. *Archives of Psychiatric Nursing*, *35*(4), 375–394.

    https://doi.org/10.1016/J.APNU.2021.05.002

Musiat, P., Winsall, M., Orlowski, S., Antezana, G., Schrader, G., Battersby, M., &

    Bidargaddi, N. (2016). Paid and Unpaid Online Recruitment for Health Interventions

    in Young Adults. *Journal of Adolescent Health*, *59*(6), 662–667.

    https://doi.org/10.1016/J.JADOHEALTH.2016.07.020

O'Donnell, M. L., Alkemade, N., Creamer, M. C., McFarlane, A. C., Silove, D., Bryant, R.

    A., & Forbes, D. (2016). The long-term psychiatric sequelae of severe injury: a 6-year

    follow-up study. *The Journal of Clinical Psychiatry*, *77*(4), e473-9.

    https://doi.org/10.4088/JCP.14M09721

Ogle, C. M., Rubin, D. C., Berntsen, D., & Siegler, I. C. (2013). The Frequency and Impact

    of Exposure to Potentially Traumatic Events Over the Life Course. *Clinical*

    Psychological Science : A Journal of the Association for Psychological Science, *1*(4),

    426–434. https://doi.org/10.1177/2167702613485076

Pedersen, E. R., & Paves, A. P. (2014). Comparing perceived public stigma and personal stigma of mental health treatment seeking in a young adult sample. *Psychiatry Research*, *219*(1), 143–150. https://doi.org/10.1016/J.PSYCHRES.2014.05.017

Perestelo-Perez, L., Torres-Castaño, A., González-González, C., Alvarez-Perez, Y., Toledo-Chavarri, A., Wagner, A., Perello, M., van der Broucke, S., Díaz-Meneses, G., Piccini, B., Rivero-Santana, A., & Serrano-Aguilar, P. (2020). IC-health project: Development of MOOCs to promote digital health literacy: First results and future challenges. *Sustainability (Switzerland)*, *12*(16). https://doi.org/10.3390/SU12166642

Prochaska, J. O., & Diclemente, C. C. (1982). Transtheoretical therapy: Toward a more integrative model of change. *Psychotherapy*, *19*(3), 276–288. https://doi.org/10.1037/h0088437

Qiu, J., Shen, B., Zhao, M., Wang, Z., Xie, B., & Xu, Y. (2020). A nationwide survey of psychological distress among Chinese people in the COVID-19 epidemic: implications and policy recommendations. *General Psychiatry*, *33*(2). https://doi.org/10.1136/GPSYCH-2020-100213

Reed, D. J. (2016). Coping with occupational stress: the role of optimism and coping flexibility. *Psychology Research and Behavior Management*, *9*, 71. https://doi.org/10.2147/PRBM.S97595

Renneberg, B., Erken, J., & Kaluza, G. (2009). Stress. In J. Bengel & M. Jerusalem (Eds.), *Handbuch der Gesundheitspsychologie und Medizinischen Psychologie [Handbook of health psychology and medical psychology]* (pp. 139–146). Hogrefe.

Rheker, J., Andersson, G., & Weise, C. (2015). The role of "on demand" therapist guidance vs. no support in the treatment of tinnitus via the internet: A randomized controlled

trial. *Internet Interventions*, *2*(2), 189–199.

https://doi.org/10.1016/J.INVENT.2015.03.007

Ritchie, H., Mathieu, E., Rodés-Guirao, Lucas Appel, C., Giattino, C., Ortiz-Ospina, E.,

Hasell, J., Macdonald, B., Beltekian, D., & Roser, M. (2022). *Coronavirus Pandemic*

(COVID-19). Our World in Data. https://ourworldindata.org/coronavirus

Sanchez-Gomez, M., Giorgi, G., Finstad, G. L., Urbini, F., Foti, G., Mucci, N., Zaffina, S.,

& León-Perez, J. M. (2021). COVID-19 Pandemic as a Traumatic Event and Its

Associations with Fear and Mental Health: A Cognitive-Activation Approach.

International Journal of Environmental Research and Public Health 2021, Vol. 18,

Page 7422, *18*(14), 7422. https://doi.org/10.3390/IJERPH18147422

Sareen, J., Jagdeo, A., Cox, B. J., Clara, I., ten Have, M., Belik, S. L., de Graaf, R., & Stein,

M. B. (2007). Perceived barriers to mental health service utilization in the United

States, Ontario, and the Netherlands. *Psychiatric Services (Washington, D.C.)*, *58*(3),

357–364. https://doi.org/10.1176/PS.2007.58.3.357

Schacter, D. L., Addis, D. R., Hassabis, D., Martin, V. C., Spreng, R. N., & Szpunar, K. K.

(2012). The Future of Memory: Remembering, Imagining, and the Brain. *Neuron*,

76(4), 677–694. https://doi.org/10.1016/J.NEURON.2012.11.001

Schwarzer, R., & Luszczynska, A. (2008). How to overcome health-compromising

behaviors: The health action process approach. *European Psychologist*, *13*(2), 141–

151. https://doi.org/https://doi.org/10.1027/1016-9040.13.2.141

Schwarzer, R., & Luszczynska, A. (2012). Stressful Life Events. In I. B. Weiner, A. M.

Nezu, C. M. Nezu, & P. A. Geller (Eds.), *Handbook of Psychology, Volume 9, Health*

Psychology, Second Edition (pp. 29–56). John Wiley & Sons, Ltd.

https://doi.org/10.1002/9781118133880.HOP209002

Selye, H. (1936). A Syndrome produced by Diverse Nocuous Agents. *Nature*, *138*, 32.

https://doi.org/10.1038/138032a0

Selye, H. (1956). *The Stress of Life*. McGraw-Hill.

Sickel, A. E., Seacat, J. D., & Nabors, N. A. (2015). Mental health stigma update: A review

of consequences. *Http://Dx.Doi.Org/10.1080/18374905.2014.11081898*, *12*(3), 202–

215. https://doi.org/10.1080/18374905.2014.11081898

Siegenthaler, F. (2011). *Psychische Gesundheit und Rückkehr zur Arbeit von Verletzten*

nach leichten und moderaten Unfallereignissen-Prädiktoren für die Früherkennung

komplizierter Heilungsverläufe [Mental health and return to work of injured persons

after minor and moderate accid.

https://biblio.unibe.ch/download/eldiss/11siegenthaler_f.pdf

Soklaridis, S., Lin, E., Lalani, Y., Rodak, T., & Sockalingam, S. (2020). Mental health

interventions and supports during COVID- 19 and other medical pandemics: A rapid

systematic review of the evidence. *General Hospital Psychiatry*, *66*, 133.

https://doi.org/10.1016/J.GENHOSPPSYCH.2020.08.007

Sokratous, S., Merkouris, A., Middleton, N., & Karanikola, M. (2013). The association

between stressful life events and depressive symptoms among Cypriot university

students: A cross-sectional descriptive correlational study. *BMC Public Health*, *13*(1),

1–16. https://doi.org/10.1186/1471-2458-13-1121/TABLES/7

Solberg Nes, L., & Segerstrom, S. C. (2006). Dispositional optimism and coping: A meta-analytic review. *Personality and Social Psychology Review*, *10*(3), 235–251. https://doi.org/10.1207/s15327957pspr1003_3

Sotoudeh, H. G., Alavi, S. S., Akbari, Z., Jannatifard, F., & Artounian, V. (2020). The Effect of Brief Crisis Intervention Package on Improving Quality of Life and Mental Health in Patients with COVID-19. *Iranian Journal of Psychiatry*, *15*(3), 205–212. https://doi.org/10.18502/IJPS.V15I3.3812

Spek, V., Cuijpers, P., NykIíček, I., Riper, H., Keyzer, J., & Pop, V. (2007). Internet-based cognitive behaviour therapy for symptoms of depression and anxiety: a meta-analysis. *Psychological Medicine*, *37*(3), 319–328. https://doi.org/10.1017/S0033291706008944

Sritharan, J., & Sritharan, A. (2020). Emerging Mental Health Issues from the Novel Coronavirus (COVID-19) Pandemic. *Journal of Health and Medical Sciences*, *3*(2). https://doi.org/10.31014/AIOR.1994.03.02.109

Udayar, S., Urbanaviciute, I., Morselli, D., Bollmann, G., Rossier, J., & Spini, D. (2021). The LIVES Daily Hassles Scale and Its Relation to Life Satisfaction. *Assessment*, 10731911211047894. https://doi.org/10.1177/10731911211047894

van der Klink, J. J., Blonk, R. W., Schene, A. H., & van Dijk, F. J. (2001). The benefits of interventions for work-related stress. *American Journal of Public Health*, *91*(2), 270–276. https://doi.org/10.2105/AJPH.91.2.270

Varma, P., Burge, M., Meaklim, H., Junge, M., & Jackson, M. L. (2021). Poor sleep quality and its relationship with individual characteristics, personal experiences and mental health during the covid-19 pandemic. *International Journal of Environmental Research and Public Health*, *18*(11). https://doi.org/10.3390/IJERPH18116030

Wahlund, T., Mataix-Cols, D., Olofsdotter Lauri, K., de Schipper, E., Ljótsson, B., Aspvall, K., & Andersson, E. (2020). Brief Online Cognitive Behavioural Intervention for Dysfunctional Worry Related to the COVID-19 Pandemic: A Randomised Controlled Trial. *Psychotherapy and Psychosomatics*, *90*(3). https://doi.org/10.1159/000512843

Wang, C., Pan, R., Wan, X., Tan, Y., Xu, L., Ho, C. S., & Ho, R. C. (2020). Immediate Psychological Responses and Associated Factors during the Initial Stage of the 2019 Coronavirus Disease (COVID-19) Epidemic among the General Population in China. *International Journal of Environmental Research and Public Health 2020, Vol. 17, Page 1729*, *17*(5), 1729. https://doi.org/10.3390/IJERPH17051729

Wilson, G. T., & Zandberg, L. J. (2012). Cognitive–behavioral guided self-help for eating disorders: Effectiveness and scalability. *Clinical Psychology Review*, *32*(4), 343–357. https://doi.org/10.1016/J.CPR.2012.03.001

Wind, T. R., Rijkeboer, M., Andersson, G., & Riper, H. (2020). The COVID-19 pandemic: The 'black swan' for mental health care and a turning point for e-health. *Internet Interventions*, *20*, 100317. https://doi.org/10.1016/J.INVENT.2020.100317

Yao, H., Chen, J. H., Zhao, M., Qiu, J. Y., Koenen, K. C., Stewart, R., Mellor, D., & Xu, Y. F. (2020). Mitigating mental health consequences during the COVID-19 outbreak: Lessons from China. *Psychiatry and Clinical Neurosciences*, *74*(7), 407–408. https://doi.org/10.1111/pcn.13018

Zamboni, K., Schellenberg, J., Hanson, C., Betran, A. P., & Dumont, A. (2019). Assessing scalability of an intervention: why, how and who? *Health Policy and Planning*, *34*(7), 544–552. https://doi.org/10.1093/HEAPOL/CZZ068

5   Declaration of Originality

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Erklärung zur Dissertation

Hiermit bestätige ich, dass ich die Dissertation (Titel):

Where Shall We Begin? Factors to Consider When Developing Psychological
Interventions for Dealing With Stressful Live Events Based on the Results of Three
Research Projects

im Fach Gesundheitspsychologie und Verhaltensmedizin

unter der Leitung von Prof. Dr. Hansjörg Znoj

ohne unerlaubte Hilfe ausgeführt und an keiner anderen Universität zur Erlangung eines
akademischen Grades eingereicht habe.

Datum 31. Januar 2022   Unterschrift