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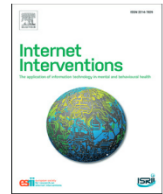
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Development of Grip self-help: An online patient-tailored self-help intervention for functional somatic symptoms in primary care

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ABSTRACT

Functional Somatic Symptoms (FSS) are somatic symptoms for which no somatic cause can be identified despite adequate diagnostic testing. FSS are common, costly, and disabling, and treatment options are limited.

Psychotherapy is one of few evidence-based treatments for FSS. Yet, this form of therapy is not widely used, since it is usually reserved for severe symptoms, requires a highly trained therapist, and is not well accepted by patients.

The current paper describes the development of the online intervention ‘Grip self-help’ and provides a description of the intervention itself. Grip self-help is an early intervention for mild to moderate FSS in primary care, which aims to reduce somatic symptoms and improve quality of life.

In the Grip self-help intervention, patients fill out a set of online questionnaires exploring unhelpful cognitions, emotions, behaviors, and social factors associated with the symptoms. Using this information, a personal profile is generated, identifying factors that might maintain FSS in that individual. As a next step, patients are offered online self-help exercises that are tailored to these factors. Guidance is offered by a primary care professional. The intervention will ultimately result in a personalized self-help guide, composed of texts that are extracted from the exercises patients found useful during the intervention.

Grip self-help is the first intervention for FSS combining the concepts of e-health, self-help, and personalized medicine. Guided by a primary care professional, patients are offered an easily accessible, yet highly personalized treatment. Grip self-help thus has the potential to meet the needs of the large group of patients with mild to moderate FSS.

1. Introduction

Functional somatic symptoms (FSS) are symptoms for which an organic cause cannot be identified despite adequate diagnostic testing. FSS are highly prevalent in all areas of medicine. FSS constitute a substantial burden for patients, are difficult to treat for doctors, and are costly for society. Untreated FSS have a high likelihood to become chronic and severely affect patients' functioning. If FSS are associated with maladaptive thoughts, feelings and behaviors, patients may fulfill the criteria of a Somatic Symptom Disorder (SSD). The estimated prevalence of SSD is 7% (Dimsdale et al., 2013), making this diagnosis more common than diabetes, coronary artery disease or depression. This underlines the need for early intervention in FSS and prevention of SSD.

Current etiological models assume that FSS are the result of an interaction between predisposing, precipitating and perpetuating factors. Predisposing factors determine the vulnerability to develop FSS, and include biological vulnerability, childhood trauma, and personality characteristics. Precipitating factors are those that initially trigger the somatic symptoms, such as infections, accidents or stressful events. Perpetuating factors are those that contribute to chronicity, including avoidance behavior, catastrophizing and complicated relations with healthcare professionals.

Psychotherapy is one of few evidence-based treatments for FSS. Psychotherapy typically targets perpetuating factors. A recent Cochrane review indicated that psychotherapy for FSS significantly reduced symptoms and increased quality of life (Van Dessel et al., 2014). However, the review also showed that existing psychotherapy protocols

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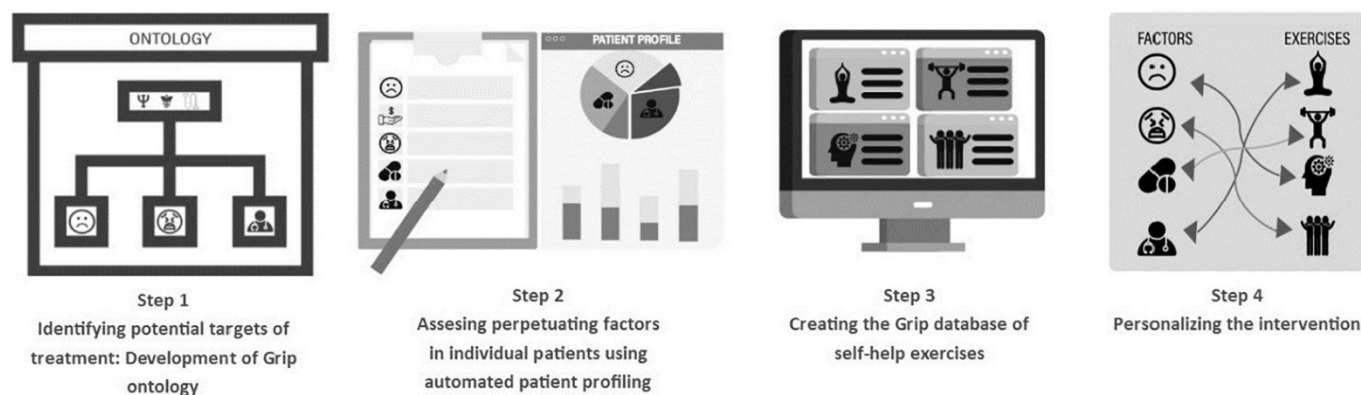


Fig. 1. Development process of Grip self-help.

do not work for everyone, and it remains unknown which type of therapy helps for whom. This is especially problematic since FSS cover an extremely heterogeneous group of patients (Rief and Martin, 2014). Patients do not only vary widely in their symptoms, but also in the degree to which specific cognitions, emotions and behaviors contribute to these symptoms. Psychotherapies thus need to be highly patient-tailored to be effective, which requires advanced clinical skills. Such skills are present in psychotherapists, but only patients with severe SSD are typically referred to a psychotherapist. In addition, referral to mental healthcare is not accepted well by patients with FSS (Van Dessel et al., 2014). The main reason for this is that psychotherapy is usually provided by a psychologist, which may not make sense to patients who seek help for somatic symptoms.

Most care for FSS is provided by General Practitioners (GPs), since somatic symptoms are initially presented to them. GPs are trained to work according to the biopsychosocial model thus placing the symptoms in a broader context. Appropriate treatment of mild to moderate FSS in primary care might prevent development of more severe SSD. However, many GPs experience difficulties with treating these patients (Reid et al., 2001). Some GPs have a negative perception or lack of empathy for patients with FSS, which might influence quality of care (Hinchey and Jackson, 2011; Hahn et al., 1996). Many GPs feel as if they lack the skills to provide the appropriate psychotherapeutic interventions. Indeed, psychotherapy offered by a GP is less effective than when offered by a psychologist (Gerger et al., 2015). In a recent analysis of videotaped consultations between GPs and patients with FSS, we observed that GPs attempted to provide advice on self-help, in accordance with the Dutch guidelines. However, they had a limited repertoire of strategies, felt insecure on which self-help strategies would benefit an individual patient, and on how to support patients with putting this advice into practice (Gol et al., 2019). This is unfortunate since our recent meta-analysis proved that self-help reduces symptoms and increases quality of life for this group of patients (Van Gils et al., 2016). Furthermore, self-help has been shown to be effective in a large range of mental disorders, such as anxiety, depression, and insomnia (Van't Hof et al., 2009; Ho et al., 2015).

In response to these difficulties, we have developed the online intervention 'Grip self-help'. Grip self-help is an online guided self-help intervention, designed to be used in primary care, aiming to reduce somatic symptoms and improve quality of life in adult patients with mild to moderate FSS.

Grip self-help aims to give patients control over their symptoms and limitations, by providing self-help strategies and asking them to evaluate which of these are helpful for them and which are not. Using automated patient profiling, perpetuating factors are identified that are relevant to the individual patient, after which the system provides a collection of exercises targeting these perpetuating factors. The self-help exercises that are offered to an individual patient might originate from various theoretical frameworks. Patients are actively involved in

the prioritization and planning of the suggested exercises. The current paper describes the methods used to develop the content of Grip self-help, as well as the intervention itself.

2. Methods used for the development of the Grip Self-help Intervention

The basic idea behind the Grip self-help intervention is to develop a tool to make expert clinical knowledge on FSS available for primary care professionals (PCPs). As a first step, concept mapping by clinicians was used to develop a hierarchical problem ontology reflecting which perpetuating factors were potential therapeutic targets in patients with FSS. As a second step, an assessment system was built to measure the relevance of the identified perpetuating factors for individual patients. As a third step, with the aid of experienced clinicians, a database was built consisting of various self-help exercises for each of these perpetuating factors. As a fourth step, patient-tailored selection of self-help exercises was enabled by algorithms, matching exercises to specific perpetuating factors. These four steps in the development of the intervention are depicted in Fig. 1.

2.1. Identifying potential targets of treatment: development of the Grip ontology of perpetuating factors in FSS

We started by developing a hierarchical problem ontology that is a comprehensive representation of perpetuating factors contributing to FSS according to the perspective of experienced clinicians. We constructed this ontology using a qualitative research method, and confirmed the identified perpetuating factors with a literature review, as described previously (Janssens et al., 2017). This hierarchical problem ontology was composed of three overarching domains of perpetuating factors: 'Hypochondria', 'Social and relational problems' and 'Symptom-related emotions and habits'. These domains comprised 16 clusters in total, each related to somatic, emotional, cognitive, behavioral, and social perpetuating factors.

2.2. Assessing perpetuating factors in individual patients using automated patient profiling

In order to assess which perpetuating factors from the ontology were relevant in a specific patient, a range of self-report questionnaires was used (see Table 1). Some of these questionnaires were developed for specific symptoms, such as the Pain Coping Inventory. In these questionnaires, we replaced the specific symptom by the general term 'physical symptoms'. Also, we adjusted the scales of the questionnaires to a universal scale, ranging from "not at all" (0), "a little bit" (1), "somewhat" (2), "quite a bit" (3), to "very" (4). To keep the number of questionnaire items to a reasonable amount, screening items were used to determine whether a more in depth exploration of a specific

Table 1
Screening items with their associated questionnaires.

Questionnaire	Screening item	Item-total correlation*
Body Consciousness Questionnaire (BCQ) subscale ‘Private body’	I am quick to sense the hunger contractions of my stomach.	0.57
Whiteley Index (WI-7)**	Do you worry a lot about your health?	0.69
Self-Efficacy Scale (SE/SE-28)	I think that I can influence my physical symptoms.	0.67
Illness Management Questionnaire (IMQ) Factor III (Focusing on symptoms)	My physical symptoms are always at the back of my mind.	0.71
Pain Catastrophizing Scale (PCS)	I worry all the time about whether the pain will end.	0.77
Illness Cognition Questionnaire (ICQ) subscale ‘Helplessness’	My physical symptoms prevent me from doing what I would really like to do.	0.87
Illness Cognition Questionnaire (ICQ) subscale ‘Acceptance’	I can accept my physical symptoms well.	0.88
Cognitive Behavioural Responses Questionnaire (CBRQ) Subscale ‘Embarrassment avoidance’	I am ashamed of my physical symptoms.	0.84
Cognitive Behavioural Responses Questionnaire (CBRQ) Subscale ‘All-or-nothing behavior’	I tend to overdo things and then rest up for a while.	0.69
Tampa scale for Kinesiophobia (TSK-11) subscale ‘somatic focus’	My physical symptoms have put my body at risk for the rest of my life.	0.61
Tampa scale for Kinesiophobia (TSK-11) subscale ‘activity avoidance’	Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my physical complaints from worsening.	0.81
Pain Coping Inventory (PCI) Subscale ‘Distraction’	When I have physical symptoms, I do something I find pleasant.	0.73
Pain Coping Inventory (PCI) Subscale ‘Worrying’	I think that the pain will worsen.	0.63
Pain Coping Inventory (PCI) Subscale ‘Pain transformation’	When I have physical symptoms, I imagine the pain less violent than it really is.	0.74
Pain Coping Inventory (PCI) Subscales ‘Resting and retreating’	When I have physical symptoms, I take rest by sitting or lying down.	0.75
Pain Coping Inventory (PCI) subscale ‘reducing demands’	When I have physical symptoms, I continue my activities, but in a slower pace.	0.84
Toronto Alexithymia Scale (TAS-20)	I do not know what is going on inside me.	0.59
Injustice experienced questionnaire (IEQ) subscale ‘Severity/irreparability’	I feel that my physical symptoms have affected me in a permanent way.	0.78
Social Support and Pain Questionnaire (SPQ)	If I have physical symptoms, I am satisfied with how much understanding the people around me show.	0.91
Patient – Doctor Relationship Questionnaire (PDRQ-9)	My GP has enough time for me.	0.90

*Item-total correlation refers to the correlation between the score on the screening item, and the score on the total questionnaire.

**The highest correlating item for this questionnaire was “Do you find that you are bothered by many different symptoms?” (Item-total correlation = 0.70) Because this item asks for symptoms instead of a perpetuating factor, we preferred to choose the second highest correlating item.

perpetuating factor was required. If a patient scored above the threshold on the screening item, which was set at quite a bit or more for items indicating problems and a little bit or less for reversed items, the patient was requested to complete the entire questionnaire.

Screening items were selected by choosing the item with the highest item-total correlation per scale. To this end, we collected data on all of the questionnaire items from patients who visited their GP with physical symptoms. The sample consisted of 94 subjects of which 57.4% were female, ranging from 21 to 85 years old, with mean age 58.8 (SD = 14.5). The item-total correlations between screening items and the sumscores of their corresponding questionnaires are presented in Table 1.

After a patient has filled out the online questionnaires, the results are used to automatically generate the Grip profile. This profile graphically displays which perpetuating factors are relevant for this specific patient.

2.3. Creating the Grip database of self-help exercises

After developing a method to assess perpetuating factors in individual patients, we composed a collection of self-help exercises, targeting these specific factors. The content of these exercises was inspired by the input of healthcare professionals and patients, which was gathered during several focus group meetings. The resulting collection of self-help exercises was categorized based on the goal of the exercise, such as ‘learning more about FSS’, ‘relaxation’, and ‘identifying and challenging unhelpful thoughts’. This categorization was done by two independent healthcare professionals with discrepancies being discussed until consensus, resulting in 20 categories. To explore whether patients and healthcare professionals would be willing to use these types of exercises, we asked patients (N = 138) and psychologists (N = 58) to evaluate the 20 types of exercises, using a questionnaire (scale 1–10). Results are shown in Fig. 2. Patients varied widely in their evaluations, yet the median scores did not differ much between the types of exercises. Sex, type of symptoms, and duration of symptoms

had little effect on the evaluations. Psychologists assigned a higher value to 18 out of the 20 types of exercises than patients. For patients, median scores varied from 5 to 7. For psychologists, median scores varied from 7 to 9. In order to find out what caused the wide variation in patient’s evaluations and why their overall appreciation was lower than that of psychologists, a subgroup of patients was interviewed. From the 20 patients that showed the largest variety in their evaluations of the different exercise categories on the questionnaire, we selected a subgroup of 7 patients that differed with regard to specific symptoms and age. These patients were interviewed to further explore what factors influenced the perceived usefulness of the types of exercise. These interviews showed that previous treatment experiences were a strong influence: exercise types were negatively evaluated if similar exercises were already unsuccessfully tried by the patient in the past. Yet, with the right explanation, patients were willing to try most of the exercises. This led us to decide to always involve a healthcare professional in the Grip self-help intervention to motivate and guide patients. Also, we made sure every exercise contains an explanation on how the exercise could benefit the patient.

With these results, we further developed the database of self-help exercises by inviting two clinical experts to write new exercises until the database contained at least one relevant exercise for all perpetuating factors. A third experienced clinician provided feedback in order to protect consistency across exercises. The database currently contains 60 unique exercises. The exercises are aimed at changing dysfunctional cognitions, emotions, behaviors, and social factors present in the problem ontology. The exercises were not written from the perspective of a single psychotherapeutic theoretical framework. Rather, they contain elements of cognitive behavioral therapy (CBT), acceptance and commitment therapy (ACT), and problem solving treatment (PST).

2.4. Personalizing the intervention: linking exercises to specific perpetuating factors

In order to link the exercises to perpetuating factors, we used a

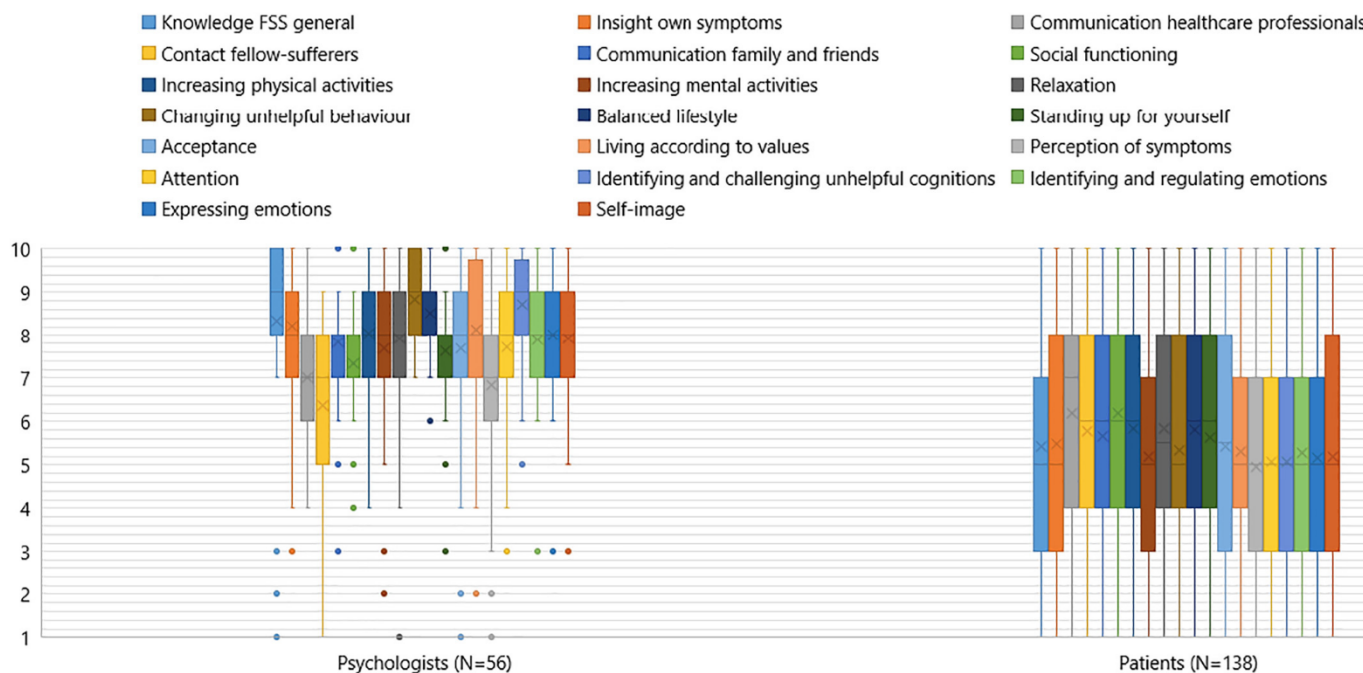


Fig. 2. Evaluation (1 – 10) of patients and psychologist of 20 types of self-help exercises.

questionnaire to ask psychologists ($N = 58$) to match the 20 types of exercises to the 16 domains of perpetuating factors from the ontology. Using these ratings, two experienced clinicians coupled exercises to perpetuating factors, with disagreements solved by consensus. The end-result of this process was an algorithm, determining for each perpetuating factor in the problem ontology which exercises would be appropriate.

We evaluated the matching of exercises to perpetuating factors with the help of eight experienced mental healthcare professionals. Based on a qualitative study describing prototypes of FSS patients (Den Boeft et al., 2016), we created five cases with video vignettes and a short description containing information on patient characteristics. These five prototypical patients varied widely with regard to relevant perpetuating factors. The clinicians were asked to indicate which factors they would target in therapy for these specific patients. Subsequently, they were provided with the type of exercises Grip self-help would suggest for each of the cases, and asked whether these would be suitable for that particular patient. Based on this evaluation, the matching between exercises and perpetuating factors was further optimized.

Grip self-help thus uses online patient profiling to automatically select a specific set of self-help exercises. Because our questionnaire results showed that psychologists and patients differed in the types of exercises they regarded as most useful, we decided to give patients the freedom and responsibility to prioritize within the automated pre-selection of exercises.

3. Description of the Grip Self-help intervention

Below, we will describe the Grip self-help intervention according to the guidelines for Executing and Reporting Internet Intervention Research (Proudfoot et al., 2011). In Fig. 3, three screenshots of the intervention are depicted.

3.1. Focus and target population

The primary target population of Grip self-help is adult patients with mild to moderate FSS, as identified by the GP. In accordance with the Dutch GP guidelines on FSS, severity is assessed based on the number of symptoms, the duration, and the degree of functional

impairment. Proficiency of the Dutch language and possession of a computer, laptop, or tablet with internet access are required to use the intervention.

3.2. Authorship details

Grip self-help was developed in The Netherlands between 2013 and 2018 by a team of researchers and computer programmers from the University Medical Center Groningen (UMCG), from 2015 onwards together with a team from technology company Nedap. The assessment system, the exercise database and the personalization algorithms are the responsibility of the UMCG team (<https://grip.health>). The interface for patients and healthcare professionals is the responsibility of the Nedap team (<http://www.nedap-healthcare.com/>). Funds for the development were provided by the Dutch Innovation Fund Health Insurances and the participating organizations; funds for the scientific evaluation of cost-effectiveness were provided by the Netherlands Organisation for Health Research and Development (Van Gils et al., 2019); funds for the scientific evaluation of implementation were provided by European Union's Horizon 2020 research and innovation program (Bühmann, Schuurmans et al., 2019).

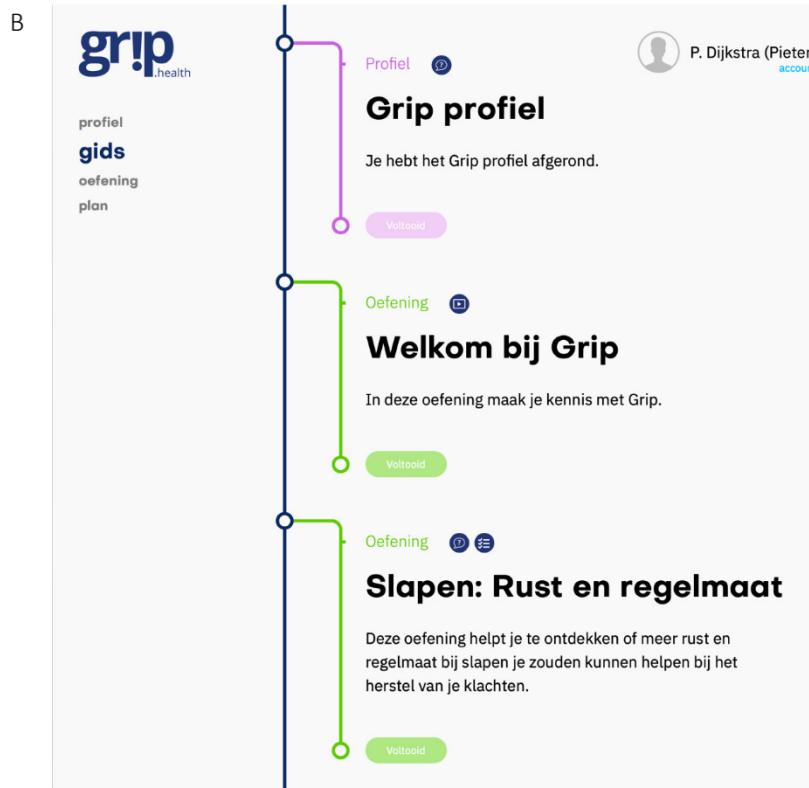
3.3. Model of change

The basic goal of Grip self-help is to enable patients to discover which self-help strategies are helpful for them and which are not. Increasing self-efficacy is the main hypothesized mechanism via which this intervention may improve outcomes such as symptom severity and quality of life.

Compared to other self-help interventions, Grip self-help does not take a certain psychotherapeutic theoretical framework or approach as a starting point. Rather, Grip self-help takes the individual patient's symptoms and perpetuating factors as a starting point and adapts its approach to these specific factors. Therefore, methods used to increase self-efficacy vary amongst patients, and will typically be based on a combination of approaches grounded in a variety of theories. Grip self-help exercises include patient education, adjusting life style, identifying and challenging unhelpful cognitions, relaxation and mindfulness exercises, learning to accept the presence of physical symptoms and



Login page.



Plan with exercises



Example of an exercise. This exercise is titled ‘Sleep: rest and regularity’. First, the goal of the exercise is described in one sentence. Further explanation on why this exercise could be useful can be found under “i” (information). Then, the actual exercise is explained.

Fig. 3. Screenshots of grip.

negative emotions, identifying values and setting goals accordingly, gradual exposure to feared activities, and managing the impact of symptoms on work and relationships. All exercises have the same structure. They start with the goal of the exercise, followed by the actual exercise, ending with a reflection on what was learned. Further explanation on why this exercise could be useful can be found under “i” (information). Fig. 3c shows an example of an exercise.

Another element that is thought to contribute to increased self-efficacy is the active involvement of the patient in the planning of the intervention. After the Grip system has made a selection of appropriate exercises, patients will have the opportunity to prioritize and decide in which order they would like to work on the exercises. This increases the chance that exercises are perceived as useful and are completed successfully, which will presumably increase motivation for and adherence to the intervention. The active involvement of the patient in decision making regarding the prioritizing and planning of exercises will shift responsibility from the healthcare professional to the patient. Figure 3b shows an example of such a plan.

3.4. Type and dose of intervention

Grip self-help is a patient-tailored online self-help intervention for mild to moderate FSS. The intervention includes registration and screening/assessment functions, and is supported by a system that enables PCPs and patients to track user progress and receive feedback. The PCP is notified when the patient has completed a questionnaire and can monitor progress by checking which exercises have been completed and when the patient last logged in.

The tailoring refers to both the contents of the intervention as well as to its duration. With regard to the contents, Grip self-help selects a set of self-help exercises tailored to the scores of the patients' personal profile. Together with the PCP guiding the intervention, patients decide which of these pre-selected exercises they are going to perform in the period until their next appointment. The exercises vary with regard to duration (one or two weeks) and intensity (varying from a single assignment to daily practice). Patients will work on one exercise at a time. The total intervention does not have a fixed duration. Patients are allowed to continue performing exercises as long as they want. Although there is no prescribed duration, we expect participants use the intervention for 10–20 weeks. During those weeks, we expect them to log in every day to work on their exercises.

On a weekly basis, patients will be asked to rate symptom severity (visual analogue scale from 0 (not intense at all) to 10 (very intense)) and symptom interference with daily life (visual analogue scale from 0 (no interference) to 10 (strong interference)). These scales are based on international recommendations on core outcome domains in this area, thus enabling future studies towards clinical effectiveness (Rief, Burton et al., 2017). These ratings also provide us with the opportunity to give automatically generated supportive feedback to the patient within the system. A detailed description of this feedback is given in paragraph 3.10.

3.5. Ethical issues

The Grip self-help intervention is only accessible for patients who are referred by their PCP. This can be a GP, or a General Practitioner Mental Health Worker (GP-MHW). Patients cannot register without a referral from their PCP, and anonymous use of the intervention is thus not possible. After referral by the PCP and providing informed consent regarding terms and regulations of use, patients can enter the Grip environment with their user name and password (see Fig. 3a). Within Grip self-help, only patients and their clinicians have access to the data. Software and data transmission security is guaranteed by Nedap. More in general, the handling of personal data is in compliance with the General Data Protection Regulation (GDPR). The Grip self-help intervention is developed for use in primary care. Therefore, the PCP always

remains responsible for the monitoring of the health of the patient, and the patient can always contact the PCP for any questions related to his or her health in general or the intervention in specific. If the results from the online questionnaires suggest mental health problems that require clinical attention, the PCP will automatically be informed.

3.6. Professional support

Patients work with Grip self-help, guided by a PCP. All exercises are offered online and do not necessarily require feedback from the PCP. The role of the PCP is mainly focused on offering support, monitoring progress, and stimulating patients' motivation. PCPs will be trained for this using an e-learning for FSS which has already been developed and piloted (Van Gils et al., 2017). In this training, it is advised to make scheduled appointments at the start of the intervention and every four to six weeks, but this is flexible and may be adjusted according to the needs of the patients and the PCP. In the first face-to-face meeting, the PCP will discuss and demonstrate the use of Grip and explain treatment goals. He or she will also support the patient in prioritizing and planning the first exercises from the preselected set. Guidance in this process is important, since for example avoidant patients might be inclined to avoid the exercises that could benefit them most, while patients high in perfectionism might prioritize the most difficult exercises already at an early stage. In the next meetings, the PCP will discuss the exercises and the progress, and the problems the patient might have encountered. In the final meeting, patient and PCP will discuss what the patient learned and changed in daily life. They will also discuss relapse prevention and look forward to the future.

Also other contact options exist apart from these scheduled appointments. The system automatically provides reminders and prompts to stimulate patients to complete their exercises. The PCP receives a warning if patients have not logged in for a while. PCPs can also provide technical support, and will be supported to do so by Nedap.

3.7. Other support

Grip self-help does not necessarily require other support, in addition to the support from a PCP. However, there are exercises that involve someone close, such as a partner, friend, or family member. Examples are exercises in which patients are instructed to ask someone to join them on their next doctor's appointment, or receive tips on how to talk about their symptoms with the people around them. All exercises in the database are labeled, depending on whether involvement of a partner, friend, or family member is necessary. This enables the PCP to adjust the plan when such a person is not available.

3.8. Program interactivity

The Grip self-help intervention includes many interactive elements. Its content is tailored to the individual user at various levels. The selection of online questionnaires that need to be completed to construct the Grip profile is based on previous answers of the patient on relevant screening questions. The patient will be able to see his or her personal profile, summarizing the perpetuating factors likely to be relevant in his or her personal situation. The system automatically pre-selects a patient-tailored set of exercises, but the patient makes the final choices and planning with regard to these exercises. Also the exercises themselves always contain interactive elements. All exercises require input of the patient in some way, including action planning, inputting self-monitoring data, tasks to complete off-line, and reflections on the learning goals of the exercise.

3.9. Multimedia channel of delivery

The Grip self-help intervention uses several multimedia channels, depending on the specific exercise. In general, we chose to vary

between different modes of channels as much as possible. Short texts tailored to the specific symptoms of the patient and graphics are used to communicate information. Video is used for education (animations), to demonstrate exercises such as progressive relaxation, and to present interviews with patients sharing their experiences. Audio instructions are included for exercises aimed at progressive relaxation and mindfulness. Automated e-mail reminders are sent to increase compliance and in case of exercises that involve self-registration. One other unique aspect of Grip self-help is that the end-product of the intervention is a personalized self-help guide. This guide is composed of texts that are extracted from the exercises patients completed during the intervention. It includes reflections of the patient on what he or she learned with regard to self-help strategies that were or were not useful for his or her own personal situation. All patients end the intervention with an exercise in which they write a foreword for their own personal self-help guide.

3.10. Degree of synchronicity

The degree of synchronicity with regard to communication differs between the various forms of communication associated with Grip self-help. The program itself provides daily motivational quotes. The PCP provides asynchronous support, in the scheduled meetings or by telephone and/or e-mail.

3.11. Audience reach

Grip is a web-application for PCPs, currently only accessible via Elise. Elise is a platform for healthcare professionals developed by Nedap, offering several applications for primary care. Elise is linked to a secure messaging service in The Netherlands called Zorgmail. This enables intercommunication between Grip, PCPs information systems and the patients' electronic health record. After the PCP has registered the patient, the patient receives an email to get access to the secure online environment where questionnaires can be filled out and exercises can be completed.

3.12. Program evaluation

Grip self-help provides the unique opportunity to construct a highly personalized treatment that can still be scientifically evaluated. The patient tailoring is based on formal algorithms, and although each patient gets his or her own unique treatment, its efficacy can be studied in a scientifically sound way. Grip self-help is currently tested in a pilot study, and (cost-)effectiveness is studied in a randomized controlled trial (RCT) (Van Gils et al., 2019). Main outcomes will be symptom severity, health-related quality of life, productivity loss and healthcare utilization and costs. Standardized outcome measures according to the EURONET-SOMA recommendations will be included (Rief, Burton et al., 2017). Process measures regarding use of the program will be collected as well. Acceptability to both PCPs and patient will be studied using qualitative and quantitative methods. In addition, implementation of Grip is studied in the context of the ImpleMentAll project. ImpleMentAll studies the effectiveness of a digitally accessible implementation toolkit (ItFits-toolkit), aiming at tailoring implementation processes of e-health services to local contexts (Buhrmann, Schuurmans et al., 2019).

4. Conclusions

FSS constitute a major burden for patients and the healthcare system. PCPs experience difficulties in providing appropriate care. Grip self-help is the first online intervention providing patient-tailored self-help for FSS. It supports PCPs in early intervention, with the aim to reduce patients' somatic symptoms and improve quality of life. Using formal algorithms, based on the knowledge of a large group of

clinicians experienced in the treatment of FSS, the intervention is personalized. Thereby, patients are offered an easily accessible, yet highly personalized treatment. Grip self-help will thus meet the needs of the large group of patients with mild to moderate FSS.

The current approach of personalization and its application in a coherent online system for guided self-help is entirely new, but the literature indicates effectiveness of its elements. Current reviews suggest that psychotherapy and self-help are effective for FSS (Van Gils et al., 2016; Van Dessel et al., 2014). Grip self-help is composed of elements of these evidence-based treatments. The unique personalization in Grip self-help can be expected to further strengthen its effectiveness, as suggested by previous studies (Van Koulik et al., 2011).

The approach used to develop Grip has several strengths. Importantly, Grip was developed in collaboration with a large group of users: both health care professionals and patients. This optimizes the chance that Grip meets the needs of patients, and that it will be implemented in daily clinical practice. This is an important issue, since implementation of e-health is often problematic (Vis et al., 2018). Another strength is the method used to develop the problem ontology that is used to personalize treatments, which was not based on a theoretical framework but rather on a systematic approach of collecting and combining clinical expertise. Our approach also has limitations that need to be taken into account. The allocation of specific exercises to particular perpetuating factors was done by two clinicians reaching consensus, based on input from other mental healthcare professionals with sometimes varying opinions. Further studies are required to optimize this exercise allocation based on the effectiveness of specific exercises in relation to the patients' personal profiles. In addition, the use of screening items reduces the questionnaire burden for patients, but might at the same time imply that questionnaires that could have provided relevant information are not provided.

In conclusion, Grip self-help empowers patients by allowing them to work on their health in a way that suits them. It makes use of modern technology and is characterized by scientific rigor. Future research has to show the effectiveness of Grip self-help in its current form and such studies are under way.

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Declaration of competing interest

The authors of this paper declare no conflict of interest.

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