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Metabolic Surgery Supporting Aftercare via Group-Intervention (MeSSAGES): study protocol of a randomised controlled trial

Eva-Maria Skoda,[1] Jasmin Steinbach ,[1] Anita Robitzsch,[1] Corinna Pfeiffer,[1] Lynik Schüren,[2] Jörg Tomaszewski,[3] Marco Niedergethman,[2] Adam Schweda,[1] Alexander Bäuerle ,[1] Martin Teufel [1]

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[1]Clinic for Psychosomatic Medicine and Psychotherapy, LVR Hospital Essen, University of Duisburg-Essen, Essen, Germany
[2]Department of Surgery, Alfried Krupp Klinikum Essen, Essen, Germany
[3]Johnson & Johnson Medical GmbH, Norderstedt, Germany

Correspondence to
Dr Eva-Maria Skoda;
eva-maria.skoda@uni-due.de

ABSTRACT

Introduction Obesity is a constantly rising and cost-intensive medical issue worldwide. Severe obesity often needs surgery to promote weight loss, but due to the rapid therapeutic success after the surgery, many patients lack the awareness of the need to consistently maintain the postoperative care. However, therapeutic success and psychological well-being can be increased through group interventions and social support of the group members. Therefore, aftercare via group intervention is a promising approach. In this prospective randomised controlled study, the self-efficacy in a social media-based interactive, psychoeducational intervention is to be tested.

Methods and analysis The intervention group will complete a social media-supported group intervention for 6 weeks with weekly postings of educative contents and the possibility to exchange in groups via anonymous avatars. The control group will receive treatment as usual (TAU) after the obesity surgery as recommended in the German S3-guidelines Obesity Surgery and Metabolic Surgery. We will examine the effectiveness of a social media-supported intervention group, and therefore, the change in self-efficacy expectation. For the primary outcome, we will perform a mixed analysis of variance with time as the within-subject factor (times of measurement T0–T4) and the group assignment as the between-subject factor (intervention +TAU vs TAU group).

Ethics and dissemination The study was approved by the Medical Association North Rhine (Ärztekammer Nordrhein, 2020031) and the patient enrolment will begin in July 2021.

Trial registration number DRKS00018089.

Strengths and limitations of this study

- ► The study is an innovative approach to assess an online-based group intervention.
- ► Cost-effective and low threshold.
- ► Much of the success depends on the motivation and self-initiative of the group.

INTRODUCTION

Background and rationales

Obesity describes an above-average increase in body fat and is based on an imbalance between energy intake and consumption.[1] Obesity is associated with a number of somatic comorbidities such as diabetes, musculoskeletal and cardiovascular diseases as well as carcinomas.[2] As a result, the life expectancy of people with obesity is considerably lower.[3 4] On a psychological level, the dysregulation of the psychoimmuno-neuroendocrine network as well as dissatisfaction with one's own body image, feelings of insufficiency and the resulting distress can result in development of depressive symptoms.[5] Prior studies could show that people with a previous depressive illness suffer from obesity more often, but also that people with obesity have an increased risk of developing major depression and other diseases from the affective spectrum.[6] Overall, people with obesity have an increased lifetime prevalence of mental illnesses.[7] Additionally, it was shown that people with an increased body mass index (BMI) often report a lower quality of life than people of normal weight.[8 9]

In the last decades, the worldwide prevalence of obesity has risen constantly.[1] In 2017, the resulting medical costs of obesity in Germany amounted to over 13 billion euros.[10 11] Established treatment options are nutritional, behavioural as well as exercise therapies with the aim of not only reducing weight but also producing long-term maintenance of weight loss.[12] In case of severe obesity, surgery is the only effective therapy in most cases, which not only leads to initially verifiable weight reduction, but also to long-term success.[13–16] In 2014, 9.225 obesity surgeries were conducted in Germany.[17] Even though obesity surgery patients benefit with

respect to weight loss and decrease in weight-related somatic disorders as well as improvements in depressive symptoms, there are still some patients at-risk for a new onset of depression and suicide.[18] Therefore, the inclusion of mental health professionals is integral to help developing and evaluating interventions with respect to possibly occurring depression symptoms, suicidal ideation and other mental health disorders after obesity surgery. Consolidating resources is particularly important with regard to therapy options for patients. There is evidence that psychological resources are associated with a lower incidence of depressive symptoms.[19]

However, the long-term outcomes largely depend on patient adherence.[20] Due to the rapid onset of measurable success after an obesity surgery, many patients lack awareness of the need to consistently maintain the recommended postoperative care. Therefore, it is important to promote compliance through innovative types of aftercare, such as group programmes, video conferences or media-based possibilities such as smartphone apps in order to allow for low-threshold access.[20 21] It has been shown that attending group meetings in which experiences can be shared and thus the experience of social support is delivered, resulting in a statistically positive effect on weight loss.[22–24]

In the 'BaSe' study, a follow-up via videoconference has caused no weight loss or increase in quality of life, but a reduction in depressive symptoms and an increase in self-efficacy.[21 25] Internet-based aftercare programmes show advantages such as flexibility in terms of time, location and broad access,[26] which means that patients who struggle with motivation or who live too far away can participate in an intervention.[27] Social networks are applications that not only enable users to formulate and pass on content themselves, but also facilitate to benefit from contributions from other users.[28] A review of recent research about social media and obesity in adults showed that social media has the potential to connect these people with social support for weight loss and that it is used not only widely but also in different kinds of ways with varying patient engagement.[29] Greater involvement of participants in the social media component predicts better outcome in weight loss.[30–32] For example, in an intervention that only took place in a private Facebook group, the number of comments and likes correlated strongly with the proportional weight loss of the participants after 12 weeks.[33] Regular provision of content that actively encourages commitment is more effective than waiting for spontaneous, unguided content. Greater number of posts reporting a healthy act, asking for help, making a plan, reporting weight or confirming other participants were associated with greater weight loss.[33] In a study in which overweight students were provided with evidence-based content on the topic of weight loss via a Facebook group, the social network proved to be a suitable and easy-to-use medium.[34] Facebook seems to be an adequate means to offer aftercare and health information, especially in the case of obesity. With one of the main functions of Facebook, namely communicating with one another,[35] it even seems ideal to reinforce a desired social support in a group setting. This is supported by the fact that Facebook already creates an environment in which users like to share information themselves.[36]

In addition, social networks offer the opportunity to minimise the aforementioned medical costs.[37] Many patients can be reached at the same time through social networks[37] without taking up the time of physicians or therapists.[38]

Successful weight loss and psychological well-being can, therefore, be promoted through group interventions and social support, which is why further research is a promising approach. However, existing offers are cost-intensive and involve much of effort.

The current study situation suggests that follow-up care after an obesity surgery is necessary to guarantee long-term success. An increasing demand due to the mounting number of surgical interventions and the need for a structured aftercare, not only surgical and dietetic but also psychotherapeutic, represents an economic challenge that can be met in group programmes. Group programmes via social networks seem to represent a low-threshold and cost-effective perspective, which facilitate therapy adherence. Despite some promising approaches, so far there is no clear empirical evidence on the topic.

A randomised controlled study with the purpose of supporting patients after obesity surgery is urgently required. Our aim is to close this gap.

Objectives and trial design

The aim of the study is to offer group-based follow-up care for patients after obesity surgery using a randomised controlled design. We expect the MeSSAGES intervention to be superior to treatment as usual (TAU) in terms of self-efficacy (primary outcomes), as well as differences in the dependent variables like weight loss (BMI), change of eating behaviour, depression symptoms, quality of life, subjective level of stress and general health status (secondary outcomes). Furthermore, acceptance and satisfaction with the intervention will be evaluated (tertiary outcomes).

METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

In general, this study protocol will be reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials guidelines for randomised controlled studies (see online supplemental table 1).

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Study setting

Our prospective randomised controlled study is designed to examine the efficacy of a psychoeducative group intervention via Facebook after an obesity surgery. The trial

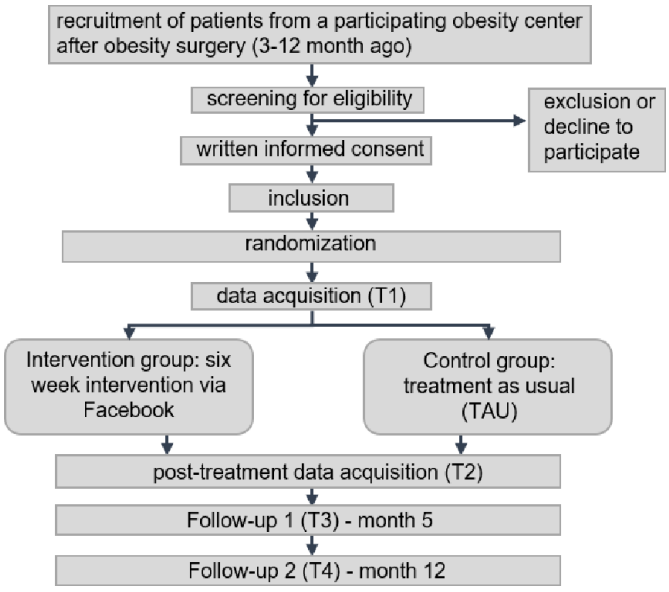

Figure 1 Participant timeline. Diagram of the study schedule with measure times T1 (preintervention), T2 (after intervention), T3 (5 months follow-up) and T4 (12-month follow-up).

flow is shown in figure 1. The intervention group (IG) will complete a Facebook-supported group intervention for 6 weeks with weekly postings of educative contents and the possibility to exchange in groups via anonymous avatars. The control group (CG) will receive regular aftercare after the surgery as recommended in the German S3-Guidelines Obesity Surgery and Metabolic Surgery (40a). Additionally, psychometric data will be collected before (T1) and after treatment (T2) as well as in a follow-up of 5 months (T3) and twelve months (T4) after the intervention.

Participant eligibility

We applied a number of eligibility criteria. Participants will be included provided that they are at least 18 years of age, had an obesity surgery due to morbid obesity (BMI >40 kg/m² or BMI >35 kg/m² with comorbidities), the surgery was 3–12 months ago, and have given their informed consent. Patients with no internet access, no or insufficient internet knowledge, unstable psychopathological conditions or insufficient knowledge of German language will be excluded.

Intervention

CG (TAU)

The study participants will be randomly assigned to the two groups—the IG and the CG (see figure 1). The CG will receive TAU, which is based on the German S3 Guidelines Obesity Surgery and Metabolic Surgery.[12] The guidelines represent the state of the art treatment for obesity surgery and metabolic surgery in Germany. This includes multidisciplinary evaluation and preparation, conservative and surgical treatment elements, and a lifelong follow-up.

Metabolic surgery supporting aftercare via group intervention

For the IG participants, pseudonymised avatar profiles will be set up on Facebook, which can be accessed via a 1 min email address. We will split the intervention group in smaller groups of 8–10 because of the different start times of patients after surgery. The avatars in the intervention will only take part in a closed Facebook group of 8–10 patients and exchange ideas with the other intervention participants in the group. An exchange with non-study participants on Facebook is not permitted and a confidentiality declaration must be filled out in advance. During the 6-week online intervention, the subjects are given an intervention unit in the Facebook group every week. Contents are psychoeducational information texts, graphs and flow charts to gain knowledge about coping strategies with binge eating, stress management, social interaction, exercise behaviour, self-worth and relapse prevention. They are intended to encourage patients to deal more intensively with their situation self-guided (without therapeutic guidance) and to share ideas with other affected persons about the topics and possible problems. Additionally, the participants are encouraged to take part in the discussions.

The topics of the intervention units are structured in (1) postoperative eating behaviour and binge eating, (2) stress management and eating behaviour, (3) social interaction and dealing with conflicts, (4) exercise behaviour/motivating aspects, (5) self-worth and (6) outlook and relapse prevention (see table 1).

Materials and instruments

The study is based on the social network and messenger-platform Facebook, where users can communicate with each other, post comments, share photographs or other contents, and group pages can be created for social exchange. For this study, we will create a closed and private group, which will be deleted at the time of the study completion. Additionally, accounts and avatars will be built for the participants and will also be deleted after the intervention. The avatars are anonymised with flower names and pictures for females and tree names and pictures for males. The study nurse's and psychologists' names are also anonymised.

Outcomes

The administration of intervention materials, access keys for accounts, introduction of group rules, and, if necessary, dialogue moderation is performed by study staff, consisting of a study nurse and a M.Sc. Psychologist. Height and weight are measured at times T1 –T4. The patients themselves convey their data via email or telephone. In addition, the patients fill out standardised psychometric online questionnaires.

These questionnaires contain basic documentation, self-efficacy, social support, eating behaviour, subjective level of stress, depression and evaluation and rating of the intervention, as shown in table 2.

Table 1 Modules of the intervention with topic, psychoeducation and skills

Module	Topic	Psychoeducation	Skills
Coping with binge eating	Postoperative eating behaviour and binge eating	Rapid and significant weight loss after obesity surgery can lead to negligence with regard to eating behaviour. It is therefore important to prevent uncontrolled eating early and consistently.	► Risk factors ► Motivation ► Relapse prevention
Stress management	Stress management and eating behaviour	Especially after a gastric resection, it is important to stay tuned and address factors that affect your weight loss and general well-being.	► Coping with stress factors ► Alternative behaviour
Social interaction	Social interaction and dealing with conflicts	When dealing with our fellow human beings, it is important to have the skills to deal with various interpersonal situations	► Social interaction skills ► Coping with conflicts
Exercise behaviour	Exercise behaviour/ motivating aspects	Even after a gastric-reducing operation, physical activity is essential to achieve and maintain a healthy body weight.	► Concrete and realistic goals ► Motivation
Self-worth	Increase self-worth	In order to strengthen self-esteem, it is important to discover and appreciate positive traits in yourself.	► Self-efficacy ► Self-worth
Relapse prevention	Outlook and relapse prevention	In order to achieve the greatest possible success after the operation, it is important to work continuously on yourself and your own behaviour in order to avoid relapses.	► Relapse prevention ► Self-efficacy

The Psychotherapy Basic Documentation (Psy-BADO) is a standardised psychosomatic-psychotherapeutic basis documentation used in the Clinic for Psychosomatic Medicine and Psychotherapy.[39] The Psy-BADO includes basic questions about demographics and therapy goals.

The general expectation of Self-Efficacy Expectation Scale (SWE) is measured with ten items on a four-point Likert-scale (0 = 'strongly disagree' to 3 = 'strongly agree').[40] SWE measures the optimistic expectation of competence, that is, the confidence in mastering a difficult situation.

The 12-Item Short-Form Survey (SF-12) is a self-reported measure assessing quality of life.[41]

The Eating Disorder Examination-Questionnaire (EDE-Q) is a 28-items questionnaire.[42] The EDE-Q is used to assess the specific psychopathology of eating disorders in adults and adolescents with the subscales Restraint, Eating Concern, Weight Concern and Shape Concern.

The Personal Health Questionnaire Depression Scale-8 (PHQ-8) measures depression symptoms with eight items from 0 = 'not at all' to 3 = 'nearly every day'.[43]

The Perceived Stress Questionnaire (PSQ) assesses general subjective burden with 30 items and seven subscales (harassment, overload, irritability, lack of joy, fatigue, worries, tension) from 0 = 'almost never' to 3 = 'usually'.[44]

Table 2 Questionnaires and times of measurement

Measures	T1: Postsurgery/ preintervention	T2: after intervention	T3: follow-up 5 months	T4: follow-up 12 months
Primary outcome				
SWE	X	X	X	X
Secondary outcome				
BMI	X	X	X	X
EDE-Q	X	X	X	X
PHQ-8	X	X	X	X
PSQ	X	X	X	X
SF-12	X	X	X	X
FSozU	X	X	X	X
Evaluation of intervention* ► Acceptance ► Satisfaction		X		

*Self-Generated Questionnaire.
BMI, body mass index; EDE-Q, Eating Disorder Examination-Questionnaire; FSozU, Social Support Questionnaire; PHQ-8, Personal Health Questionnaire Depression Scale-8; PSQ, Perceived Stress Questionnaire; SF-12, 12-Item Short-Form Survey; SWE, Self-Efficacy Expectation Scale.

The Social Support Questionnaire (FSozU) is a SF-22[45] and measures the subjective perceived social support in the social environment.

Additionally, we will use a self-generated questionnaire for evaluation of the intervention containing 43 items about the intervention modules, Facebook as an intervention platform and social exchange. The questionnaire contains open questions as well as different types of Likert scales.

Primary outcome measures

As the primary outcome, we will examine the perceived self-efficacy of a Facebook-supported group intervention in patients who underwent obesity surgery. Therefore, the change in self-efficacy expectation is measured via the SWE with 10 items at four dates (T1 before treatment, T2 directly after treatment, T3 5 months after the intervention and T4 12 months after treatment). Our primary end point will be T2 directly after the treatment. The differences between the times of measurement will be expressed as score differences.

Secondary outcome measures

As the secondary outcome, we monitor additional weight loss, change in eating behaviour, depression, quality of life, subjective level of stress and general health status measured via weight measures, EDE-Q with 28 items, PHQ-8 with eight items, the PSQ with five items, a SF of the general health status (SF-12) and a FSozU with 22 items. With the 43-item self-created questionnaire, the intervention is evaluated considering acceptance and satisfaction.

Trial timeline

We assume that the total time for patient enrolment will take approximately 2 years. The online intervention is planned for 6 weeks. Before and after, data is assessed using standardised questionnaires (T1 and T2). A third survey takes place after 5 months and 12 months (T3, T4). Thus, for the individual, the duration of the whole trial is about 12 months, of which only 6 weeks are actively spent in the intervention. For further information, see figure 1.

Sample size calculation

The goal is to recruit 80 patients (40 IG, 40 CG) through the follow-up consultation of the obesity surgery centre in Essen. We calculated the sample size by considering a correlation as a reliable approximation of the relationship between our measurement times. Jerusalem and Schwarzer[40] give a 1-year inter-rater reliability of r=0.54 for the questionnaire on general expectation of SWE, so that we consider a correlation of r=0.50 as a reliable approximation of the relationship between our measurement times. With this value, 80 test participants, an a-error of α=0.05, an effect with an effect size of f=0.155 and larger can be determined at a power of 1 – β=0.95, which, according to Cohen, is a small to medium effect size (Cohen, 1992). Small to medium effect sizes were also found for other e-health studies on psychosocial interventions (Massoudi *et al*, Lamb *et al*), so we assume that our design can reliably determine group differences over time. Even in the case of a high drop-out rate of over 35%, we would be able to discover similar effect sizes with a power of 1 – β=0.80 (with exactly 52 participants). However, we overall expect a low drop-out rate of no more than 10%, similar to other intervention studies (eg, Iacovino *et al*).

Recruitment

Patients will be recruited through the follow-up consultation of a German obesity surgery centrum by the local coordinator. Before participation, informed consent must be given.

METHODS: ASSIGNMENT OF INTERVENTIONS

Allocation and blinding

The patients are allocated to either the IG or the CG by using a random number generator. They will be informed by the clinicians or researcher who were, therefore, not blinded. There was no attempt to blind clinicians or researchers since our study is an intervention study where the clinicians and researchers managed the Facebook groups and intervention materials. However, there is no expected influence regarding to the outcome since the outcome is measured with mostly validated questionnaires and the biometrician is blinded.

METHODS: DATA COLLECTION, MANAGEMENT AND ANALYSIS

Data collection methods and management

The personal and psychological data of the online questionnaires, which is collected in connection with this study (eg, personal or psychological data and evaluations of the questionnaires), will be stored on a protected hard drive of the study director at the clinic for the duration of the data collection and evaluation. The data will be available in pseudonymised form and a code will be assigned to each patient. If necessary, a return can be made using a list of subjects. This list will be kept separately from the data, locked and only accessible to the study management. The data will be archived and stored for 10 years after trial completion and will be deleted after this time. The possibility for patients to revoke their participation and have their data deleted is set out in the data protection declaration.

Facebook as an external online social network has its own data protection guidelines that the study directors cannot influence. This poses the necessity of detailed education of the study participants about the data protection guidelines of Facebook and the obtaining of informed consent from the study participants. Participants will not use their own Facebook profiles to visit the Facebook group, but will receive pseudonymised avatars from us that do not allow any conclusions to be drawn about their own profiles. These avatars are set up with 1 min emails and a confidentiality declaration by the test subjects is drawn up with special reference to communication with other Facebook users with an anonymised avatar.

Statistical methods

Before analysis, standard tests of normality and homogeneity of variance and additional descriptive analyses of the sociodemographic data will be performed. The variables age and sex will be used to impute missing values with SPSS (IBM: V.26). For the primary analysis of the data a 2×5 mixed repeated measures analysis of variance with time as the innersubject factor (measurement times t0 to t4) and the group assignment as the between-subject factor (intervention +TAU vs TAU group) will be used. For the primary outcome, change of SWE over time between IG and CG will be compared. For the secondary outcome, change of BMI, EDE-Q, PHQ-8, PSQ, SF-12 and FSozU over time between the two groups will be examined. Additionally, the evaluation of the intervention will be put in relation to our results.

METHODS: MONITORING

Data monitoring

The data monitoring will be established by the clinics study staff and the local ethics committee.

Harms and auditing

The validated and self-generated questionnaires do not deliver specific health risks or side effects concerning patient safety. Thus, auditing is not intended. In the case of psychiatric crisis (suicidality) or somatic crisis, the study will be terminated for the subject and inpatient or stationary treatment will be initiated. It is possible that the comment function may lead to differences between the opinions of participants of the IG, which will be moderated by the study staff at all times.

ETHICS AND DISSEMINATION

Research ethics

The study was approved by the Medical Association North Rhine (Ärztekammer Nordrhein, 2020031) and the intervention will begin in summer, 2021.

Protocol amendments

Important protocol modification will be communicated to the Medical Association North Rhine.

Consent or assent

The study staff (coordinator of the obesity surgery centre) will contact potential participants and obtain written informed consent.

Confidentiality

To protect confidentiality, the participant's data will be pseudonymised and stored for at least 10 years. The pseudonymised data will be in a locked file.

Declaration of interest

The authors declare that they have no financial or competing interest.

Access to data

The database is only accessible for the study staff and researchers of the project.

Ancillary and post-trial care

Not applicable.

Dissemination policy

Results will be disseminated in peer-reviewed journals as well as conference presentations.

DISCUSSION

Obesity is a constantly increasing and cost-intensive medical issue worldwide because of its long-time somatic consequences, increased lifetime prevalence of mental illnesses and comorbidities in general (1–10, 15, 16). Obesity surgery is the most effective treatment and hence important to reduce the overall medical issues and psychological health problems in long term. Accordingly, retained effects depend on psychological factors, especially compliance (21). Compliance and self-efficacy can be enhanced by (social network) group meetings and its social support. Facebook is a frequently used social platform, which is cost-effective as well as low-threshold and can be used as an easy-to-use aftercare for patients after an obesity surgery. The feasibility of this kind of intervention shall be tested in the present intervention study.

The MeSSAGES study seeks to assess the effectiveness of a low-threshold and cost-effective psychological follow-up care after obesity surgery with Facebook as a platform. Healthcare system should respond to these needs of a low-threshold, cost-effective intervention. Since only few data exists to this point of time, our study has relevance. The findings on the applicability and manageability of this medium as an aftercare intervention are made possible with the MeSSAGES study. A previous study indicated that a follow-up after-treatment-group via videoconference leads to a reduction in depressive symptoms, but no differences in weight loss.[21] We expect MeSSAGES to prove the effectiveness of the Facebook-supported group intervention with a positive change in self-efficacy expectation and additionally, weight loss, a change in eating behaviour, depression, quality of life, subjective level of stress and general health status.

One limitation of the study is that much of the intervention's success depends on the motivation and self-initiative of the group participants. Furthermore the researchers (except for the biometrician) are not blinded. However, we do not expect any influence regarding the outcome since the patients are pseudomyzed in the Facebook groups, but in future studies an examining approach could be integrated. Further studies could also expand the approach and examine the effectiveness of group interventions in other social media platforms. Overall, the MeSSAGES study is an innovative, novel approach and the outcome is yet to be evaluated.

Contributors E-MS designed the study initially, developed the intervention and administered the trial. She helped with the manuscript as well as accepts full responsibility for the finished work and controlled the decision to publish. JS contributed to designing the study. She provided the draft and adapted it. She is trial site investigators who contributed to refinement of the study design and protocol, implementation of the trial and who are involved regarding patient recruitment, treatment and data collection. AR contributed to designing the study and helped with the manuscript. She is trial site investigators who contributed to refinement of the study design and protocol, implementation of the trial and who are involved regarding patient recruitment, treatment, and data collection. CP contributed to designing the study and helped with the manuscript. She is trial site investigators who contributed to refinement of the study design and protocol, implementation of the trial and who are involved regarding patient recruitment, treatment and data collection. LS contributed to designing the study and helped with the manuscript. She is trial site investigator who contributed to refinement of the study design and protocol, implementation of the trial and who are involved regarding patient recruitment, treatment, and data collection. JT contributed to designing the study and helped with the manuscript. He is trial site investigator who contributed to refinement of the study design and protocol, implementation of the trial and who are involved regarding patient recruitment, treatment, and data collection. MN contributed to designing the study and helped with the manuscripts. He is trial site investigator who contributed to refinement of the study design and protocol, implementation of the trial and who are involved regarding patient recruitment, treatment, and data collection. AS provided statistical and methodical expertise in trial design and is the principal trial statistician. AS is responsible for data management during the trial. AB and MT are shared last author. They initiated the study and contributed to designing the study. They further adapted the intervention and the manuscript draft. All authors revised the manuscript critically and approved the final version to be published. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. AB and MT are joint last authors.

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ORCID iDs
Jasmin Steinbach http://orcid.org/0000-0002-2738-4089
Alexander Bäuerle http://orcid.org/0000-0003-1488-8592
Martin Teufel http://orcid.org/0000-0003-2120-1840

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