SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description/Page
Administrative information		
Title	1	Page 1
Trial registration	2a	Page 2
	2b	See table below
Protocol version	3	Page 22
Funding	4	Page 23
Roles and responsibilities	5a	Page 1 & Page 23
	5b	University of Freiburg Department of Rehabilitation Psychology and Psychotherapy Institute of Psychology Engelbergerstr. 41, 79085 Freiburg, Germany
	5c	This trial is investigator-initiated. The sponsor (University of Freiburg) and funding source (German Research Foundation) had no role in the design of this study. Sponsor and funding source will have no role during trial execution, analyses, interpretation of the data, or decision to submit results.
	5d	LK is the principal investigator. CMW is responsible for recruitment and data acquisition. JB and TZ supervise the recruitment of participants. JB is responsible for all aspects of local organisation including identifying potential recruits and taking consent. CMW, JB and TZ meet weekly throughout the trial to oversee trial conduct and recruitment. JB supervises the trial.
Introduction		
Background and rationale	6a	Pages 4-7
	6b	Pages 4-7
Objectives	7	Page 6-7

Trial design	8	Page 7

Methods: Participants, interventions, and outcomes

Study setting	9	Page 8
Eligibility criteria	10	Page 9
Interventions	11a	Pages 10-12
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Outcomes	12	Pages 12-18
Participant timeline	13	Page 7
Sample size	14	Page 18
Recruitment	15	Page 8

Methods: Assignment of interventions (for controlled trials)

Allocation:		
Sequence generation	16a	Page 10
Allocation concealment mechanism	16b	Allocation concealment is ensured as participants are not randomised until they have been included in the trial, which is after all baseline measurements have been completed.
Implementation	16c	Page 10
Blinding (masking)	17a	Page 10
	17b	In case of adverse events (e.g. acute suicidal ideation), unblinding of the telephoneinterviewer is permissible if necessary. All cases of unblinding will be documented.

Methods: Data collection, management, and analysis

Data collection methods	18a	Pages 12-18
	18b	Page 8

Data management	19	All data will be handled and stored as described in our data protection plan and ethical approval. Within the data protection plan, records of processing activities are specified.
Statistical methods	20a	Page 19
	20b	Page 19
	20c	Page 19
Methods: Monitoring		
Data monitoring	21a	A Data Monitoring Committee (DMC) has been established. The DMC is independent of the study organisers and consists of Prof. Dr Brunna Tuschen-Caffier, Prof. Dr Erik Farin-Glattacker and Prof. Dr Dr Martin Härter. The DMC will advise the project team in case of adverse events and recommend if the trial should be modified or discontinued.
	21b	Data collection will continue until the targeted sample of 128 participants is reached.
Harms	22	Pages 9-10
Auditing	23	The recruitment management group (CMW, TZ, JB) meets weekly throughout the trial to oversee trial conduct and recruitment.
Ethics and dissemination		
Research ethics approval	24	Page 2 & Page 22
Protocol amendments	25	Deviations from the study protocol will be fully documented and disclosed in further publications. In case of deviations, the protocol in the clinical trial registry will be updated.
Consent or assent	26a	Positively screened individuals receive in-depth study and data privacy information via email. All participants submit their informed consent online before study inclusion. Participants can withdraw their participation in the study at any time and request the deletion of their data as long as the data is not yet anonymised.
	26b	Participant data will not be used in ancillary studies. This trial does not involve the collection of biological specimens.
Confidentiality	27	All data will be handled and stored as described in our data protection plan and ethical approval. Rules of data security were developed with the approval of the data security officer of the University of Freiburg.
Declaration of interests	28	Page 23

Access to data	29	Only the project team in Freiburg has access to personal data. Anonymised data can be made available to other scientists based on cooperation agreements.
Ancillary and post-trial care	30	The trial centre provides no post-trial care. Generally, health care costs in Germany are covered by the health insurance companies without extra costs for the individual.
Dissemination policy	31a	Pages 19-20 & Page 22
	31b	No professional writers will be hired.
	31c	The study protocol is published in an open-access format.
Appendices		
Informed consent materials	32	All participant materials have been approved by the ethics committee and can be obtained in German from the corresponding author.
Biological specimens	33	No biological specimens are collected.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

WHO Trial Registration Data Set (Version 1.3.1)		
1	Primary Registry and Trial Identifying Number	German Clinical Trials Register; Main ID: DRKS00024349
2	Date of Registration in Primary Registry	29/01/2021
3	Secondary Identifying Numbers	N/A
4	Source(s) of Monetary or Material Support	German Research Foundation
5	Primary Sponsor	University of Freiburg Department of Rehabilitation Psychology and Psychotherapy Institute of Psychology Engelbergerstr. 41, 79085 Freiburg, Germany
6	Secondary Sponsor(s)	N/A
7	Contact for Public Queries	Name: Claudia Mueller-Weinitschke Address: Engelbergerstr. 41 79085 Freiburg Germany Telephone: 07612039439 Email: interaktiv@psychologie.uni-freiburg.de Affiliation: University of Freiburg, Department of Rehabilitation Psychology and Psychotherapy , Institute of Psychology
8	Contact for Scientific Queries	Name: Lena Krämer Address: Engelbergerstr. 41 79085 Freiburg Germany Telephone: 07612039315 Email: kraemer@psychologie.uni-freiburg.de Affiliation: University of Freiburg, Department of Rehabilitation Psychology and Psychotherapy , Institute of Psychology
9	Public Title	Behavioral activation based on the Health Action Process Approach – Efficacy of a theory-based online intervention in depression
10	Scientific Title	Behavioral activation based on the Health Action Process Approach – Efficacy of a theory-based online intervention in depression - InterAKTIV
11	Countries of Recruitment	Germany
12	Health Condition(s) or Problem(s) Studied	F32 - Depressive episode
13	Intervention(s)	Intervention 1: Intervention group: Participants receive access to the web-based intervention, comprising 7 modules (45 minutes each, plus an introductory module), daily motivating SMS, weekly homework assignments, and weekly feedback from a psychologist.

		Participants of the intervention group have unrestricted access to other health care services. Intervention 2: Control group: Participants of the control group receive access to the web-based intervention after follow-up assessments. Participants of the control group have unrestricted access to other health care services.
14	Key Inclusion and Exclusion Criteria	Inclusion criteria: Depression diagnosis in clinical interview Exclusion criteria: current psychotherapy, current change of psychopharmaceuticals, exclusion diagnosis Age minimum: 18 Years Age maximum: 65 Years Gender: Both, male and female
15	Study Type	interventional
16	Date of First Enrollment	08/02/2021
17	Sample Size	128
18	Recruitment Status	Pending
19	Primary Outcome(s)	Primary outcome is the change of depression severity, measured by the QIDS (Quick Inventory of Depressive Symptomatology, externally assessed during the telephone interview), between baseline (t1) and post-intervention (t2, eight weeks after randomization). In addition, depression severity will be assessed at follow-up (t3, six months after randomization).
20	Key Secondary Outcomes	1. Remission of depression (SCID-1, Structured clinical interview for DSM-V) 2. Depression response (PHQ-9; Patient Health Questionnaire-9) 3. Actitity behavior: Everyday activity (BADS; Behavioral Activation for Depression Scale) 4. Activity behavior: Physical activity (IPAQ-SF; International Physical Activity Questionnaire - Short Form) 5. Motivational and volitional indicators (outcome expectancies, motivational self-efficacy, intention, volitional self-efficacy, action planning, coping planning, action control) 6. Perseverative cognitive processes (RSQ-D; Response Style Questionnaire – German Version) 7. Side effects of the intervention (INEP; Inventar zu Erfassung negativer Effekte von Psychotherapie) All assessments take place at baseline (t1), eight weeks (t2) and six months after randomization (t3).

		Covid-19-related limitations are recorded at all three time points (self-report). Additionally, sociodemographic information and the initial motivational level will be assessed at baseline (t1; self-report). At t2, received health care services (FIMA) as well as satisfaction with the intervention will be assessed.
21	Ethics Review	Status: approved Approval date: 19/11/2020 Contact: (leading) Ethics Committee-No. 20-1045 (Ethik-Kommission der Albert-Ludwigs-Universität Freiburg)
22	Completion date	N/A
23	Summary Results	N/A
24	IPD sharing statement	It is planned to make the anonymised evaluation data set available to external scientists for research purposes on the basis of cooperation agreements.