ONLINE SUPPLEMENTARY MATERIALS

Supplement 1. SF-GAPI modules

Participants randomized to the experimental group receive SF-GAPI modules over the course of three months. Guidance is offered via chat services in the app by trained experts by experience: individuals who experienced depressive-, or anxiety disorder and now use this experience to help others. They have at least a post-secondary vocational education, and receive an individual training to work according to study protocol. The training includes information about the StayFine study and content of the SF-GAPI modules, use of online feedback, and role playing for providing positive feedback. Regular meetings between experts by experience and a researcher with clinical experience are scheduled to discuss any questions and working with the protocol.

Most SF-GAPI modules consist of two parts. Progression to a subsequent part of a module is only possible after feedback from the expert by experience. This enables interaction regarding new information and the exercises. Each module (except for the first and last) also has an optional diary that can be activated after completion of the module, for which reminders are set once a week. Repetition may help to keep the most important aspect of the module in mind.

Psycho-education

This module includes information about relapse prevention of depressive-, and anxiety disorders. It informs participants about the importance of relapse prevention: it may help to strengthen oneself and enhance positive thinking and feelings. Additionally, the participant's expert by experience is introduced and information is provided about how the modules can be used. This module is an adaptation of PCT[87], enriched with examples of adolescent life and information about anxiety relapse prevention.

Cognitive restructuring

The main component of the cognitive restructuring module is the identification of rigid dysfunctional attitudes and schemas, followed by the evaluation of dysfunction beliefs by activating a positive network with help of positive affect. Wishful beliefs using phantasy and imagination techniques will be explored that activate positive affect.[86] This module is an ingredient of PCT[87] as has been found effective in several RCT's for relapse prevention in adults in remission of recurrent depressive disorders.[53–58]

Enhancing positive affect

Enhancement of the autobiographical memory of positive affect and memories using a positive diary and affect labeling is practiced in this module. Using a positive diary participants practice with detailed descriptions of positive experiences. This module is based on the positive diary used in PCT[87] and includes examples for adolescents with a history of both depressive-, and anxiety disorders.

Behavioural activation

Relapse of depressive-, and anxiety disorders can be prevented by recognizing the intensity of depressive-, or anxious affect and using distraction to improve one's mood.[68] Staying fine is practiced by providing psycho-education about undertaking (simple) activities and presenting options for fun activities, relaxing, soothing, sports[126], social contacts or doing something that one is successful at. Participants are challenged to choose activities and evaluate how the activity affected their mood.

Exposure

Relapse of anxiety can be prevented by building a strong network of different positive or non-threatening associations through experience.[127] This means that a person who used to be anxious and avoidant, needs to keep on facing previously and currently challenging situations to disconfirm anxious beliefs, to accept the anxious feeling as non-threatening, and to diminish experiental avoidance. In this module, information is provided about anxiety,

avoidance and the prevention of relapse, and participants are challenged to practice with exposure in multiple situations.

Sleep

Sleep is associated with depressive-, and anxiety disorders and has been found to (negatively) affect treatment outcome.[128] In addition, sleep disturbance is often a residual symptom of adolescent depression.[129,130] Therefore, this module contains psycho-education about common changes in development, how this affects sleep and what the overall role of sleep is. Next to psycho-education, exercises and tips are included to improve sleeping behaviour using sleep registration, sleep restriction[81], relaxation and cognitive restructuring.

Wellness

Ryff and Singer[131] have described wellness as a continuum that can be affected by six dimension 1) self-acceptance, 2) positive relations with others, 3) autonomy, 4) environmental mastery, 5) purpose in life and 6) personal growth. These dimensions are implicitly promoted in all modules, but psycho-education and focus is provided in this Wellness module. In accordance with Kennard and colleagues[68] we included exercises to enhance social contact, challenge goals and ideas about spirituality (altruism and optimism) and by promoting finding a balance between relaxation and activity. Relaxation exercises are adapted from King.[132]

StayFine plan

In this last module, participants make a personalised relapse prevention plan or 'StayFine plan'. By using reflective questions and an open field for each module, participants are encouraged to go back to previous modules (their favourite pages, diaries and feedback) in order to make their StayFine plan that they can consult at any time. This easy access plan provides them with a useful tool to stay fine. The StayFine plan is an adaptation of the plan in

PCT[87], enriched with examples of anxiety and adolescent life, as well as with 'lessons learned' from the different modules.

Supplement 2. Personalisation procedure

The SF-GAPI modules are personalised to the individual based on: 1. previous mental disorder (i.e. depressive-, anxiety disorders, or both), 2. the level of positive/negative affect, sleep problems and flourishing, 3. an individual symptoms network, and 4. shared decisions making between the guiding expert by experience and the participant.

The previous mental disorder is retrieved from the diagnostic interview. Following a history of anxiety disorder, the Exposure module is advised. Following a history of depressive disorder, the Behavioural activation module is advised. When there is a history of both depressive-, and anxiety disorders, the advice can include both Exposure and Behavioural activation.

Online questionnaires, lead to the advice to include the 1. Wellness module when flourishing (measured with the MHC-SF)[118] is low, 2. Enhancing positive affect module when positive affect (measured with the PANAS)[108,109] is low, and 3. Sleep module when sleep deprivation (measured with the SRSQ)[114] is high.

The fluctuations in affect and thoughts of the SF-MON are used as input for an individual symptom network. A direct link between the depressive-, or anxiety affect variable and another variable in the network, is used to advice on one of the modules: Exposure, Behavioural activation, Enhancing positive affect, Sleep and Wellness. For example, when ‘feeling alone’ is directly linked to ‘feeling anxious’ or ‘feeling depressed’, the Wellness module is advised.

The final advice depends on the above outcomes and predefined possible combinations (see Figure 2). Combination 1 and 4 are mostly advised when less than three of the five modules are recommended based on the outcomes. Combination 7 and 8 are recommended with the notion that the combination of Behavioural activation and Exposure are possibly more time consuming than other combinations. When more than one

combination is possible, a researcher lists which combinations are a first or second choice. The expert by experience and participant schedule a call to discuss the advice and choose a combination of modules through shared decision making.

Supplement 3. SPIRIT checklist

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**	**Addressed on page number**
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3, 21
	2b	All items from the World Health Organization Trial Registration Data Set	https://www.trialregister.nl/trial/8237 ClinicalTrials.gov: NCT05551468
Protocol version	3	Date and version identifier	20
Funding	4	Sources and types of financial, material, and other support	23
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1+22-23
	5b	Name and contact information for the trial sponsor	23

	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	23
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	19-23
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-9
	6b	Explanation for choice of comparators	12+14-15
Objectives	7	Specific objectives or hypotheses	8-9
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	9
Methods: Participants, interventions, and outcomes			

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	12
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	11-13
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10+14-15 + Figure 1 + Supplement 1+2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	14
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	14-15 + Supplement 1
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	15-17
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table 1 (p. 10) + Figure 1

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12-13
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	14-15
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	14-15
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	14-15
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	14-15
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	14-15

Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	15-18
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14-15
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	20
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	18-20
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	19-20
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	19-20
Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	20
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	16-17
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	3+20
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	20-21
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	11-12
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A

Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	20
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	23
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	23
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	3+20-21
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	23
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplement 4.
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

Supplement 4. Informed consent materials

Toestemmingsformulier proefpersoon

StayFine onderzoek: terugvalpreventie van angst en depressie bij jongeren

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen of te stoppen met het onderzoek. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het verzamelen en gebruiken van mijn gegevens voor de beantwoording van de onderzoeksvraag in dit onderzoek. Ik geeft toestemming voor het verwerken van de KSADS informatie via een dataserver in de Verenigde Staten. Ik weet dat mijn gegevens 15 jaar worden bewaard.
- Ik weet dat voor de controle van het onderzoek sommige mensen toegang tot al mijn gegevens kunnen krijgen. Die mensen staan vermeld in deze informatiebrief. Ik geef toestemming voor de inzage door deze personen.
- Ik geef toestemming om mij te informeren over onverwachte bevindingen zoals dreigende terugval.
- Ik geef ☐ **wel**

  ☐ **geen**

  toestemming om mijn persoonsgegevens langer dan 15 jaar te bewaren en te gebruiken voor toekomstig onderzoek op het gebied van terugvalpreventie van angst en/of depressie.
- Ik geef ☐ **wel**

  ☐ **geen**

  toestemming om mij na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek.
- Ik geef ☐ **wel**

  ☐ **geen**

  toestemming om audio-opnames / video-opnames * te maken van de KSADS interviews.

  *doorhalen wat niet van toepassing is.

- Ik wil ☐ **wel**

  ☐ **niet**

  geïnformeerd worden over de resultaten van dit onderzoek.

- Ik vraag ☐ **wel**

  ☐ **geen**

  StayFine-vriend om mij bij te staan tijdens deelname aan dit onderzoek.

- Ik wil meedoen aan dit onderzoek.

Naam proefpersoon:

Handtekening:
Datum :

Ik verklaar dat ik deze proefpersoon volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de proefpersoon zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

Naam onderzoeker (of diens vertegenwoordiger):

Handtekening:
Datum:

Toestemmingsformulier ouders of voogd

StayFine onderzoek: terugvalpreventie van angst en depressie bij jongeren

Ik ben gevraagd om toestemming te geven voor deelname van mijn kind aan dit medisch-wetenschappelijke onderzoek:

Naam proefpersoon (kind):
Leeftijd: _____ Jaar

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik wil dat mijn kind meedoet.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen dat mijn kind toch niet mee doet. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming voor het verzamelen en gebruiken van de gegevens van mijn kind voor de beantwoording van de onderzoeksvraag in dit onderzoek. Ik weet dat de gegevens van mijn kind 15 jaar worden bewaard.
- Ik weet dat voor de controle van het onderzoek sommige mensen toegang tot alle gegevens van mijn kind kunnen krijgen. Die mensen staan vermeld in deze informatiebrief. Ik geef toestemming voor die inzage door deze personen.
- Ik geef toestemming om mij en mijn kind te informeren over onverwachte bevindingen zoals dreigende terugval.
- Ik geef ☐ **wel**

  ☐ **geen**

  toestemming om de persoonsgegevens van mijn kind langer te bewaren dan 15 jaar en te gebruiken voor toekomstig onderzoek op het gebied van terugvalpreventie van angst en depressie.
- Ik geef ☐ **wel**

  ☐ **geen**

  toestemming om mijn kind na dit onderzoek opnieuw te benaderen voor een vervolgonderzoek.
- Ik wil ☐ **wel**

  ☐ **niet**

  geïnformeerd worden over in welke groep mijn kind zat.

- Ik geef ☐ **wel**

  ☐ **geen**

  toestemming om audio-opnames / video-opnames * te maken van de KSADS interviews.

- Ik ga ermee akkoord dat mijn kind meedoet aan dit onderzoek.

Naam ouder/voogd**:

Handtekening:
Datum:

Naam ouder/voogd**:

Handtekening:
Datum:

Ik verklaar hierbij dat ik bovengenoemde persoon/personen volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de ouder of voogd zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

Naam onderzoeker (of diens vertegenwoordiger):
_____

Handtekening:
Datum: : __ __ - __ __ - __ __ __ __

Supplement 5. References used in supplements

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