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Study protocol: The effect of motivational interviewing on self-management in adult kidney transplant recipients (MIAKTR)

Cigdem Erdem, Fatma Cebeci[1]

Abstract:

BACKGROUND: The aim of the study is to examine the effect of motivational interview sessions on self-management that will be conducted in accordance with the post-discharge requirements of adult kidney transplant recipients. Patient-centered motivational interviews make a significant contribution to activating patients' sense of being capable of changing to realize their self-management.

MATERIAL AND METHODS: This study is a single-center, single-blind, prospective randomized controlled trial. The participants of the study will consist of 80 kidney transplant recipients at an organ transplant center in Turkey. The study is a randomized controlled trial compatible with SPIRIT. The CONSORT flow diagram has been used in this study protocol. The sample will consist of participants within the 3rd, 4th, 5th, and 6th months after the kidney transplant. The measurements will be performed in the first and third months after the interviews. The study continues via the collection of data from the intervention and control groups.

CONCLUSION: In order to support or improve the self-management of kidney transplant recipients, new tools are required that are suitable for this population. Patient-centered motivational interviews can make a significant contribution to activating patients' sense of being capable of changing to realize their self-management. The first motivational interview program to promote a healthy lifestyle in kidney transplant recipients, prevent unwanted conditions after transplantation, and improve self-management will be used in this study. After the intervention has been developed, we expect improvements in self-management with a motivational interviews through creating their own strategies for behavioral changes and improvements in health outcomes.

Keywords:

Kidney transplantation, motivational interviewing, randomized controlled trial, self-management

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Introduction

Kidney transplant recipients have important responsibilities in coping with the new process. Self-management, defined as the ability of an individual to cope with the symptoms, treatment, physical and social consequences of their illnesses, and lifestyle changes, is at the forefront in terms of coping with the emerging conditions after transplantation.[1-3] Patients need to be monitored for a long time in terms of maintaining their graft health and various problems.[4] Support programs are needed to improve the knowledge and skills of recipients in order to monitor themselves. Supportive approaches lead to improved quality of life in kidney transplant patients.[5] It is an important requirement for recipients to have appropriate self-management behaviors for their survival and the graft. Thus, the quality of life is improved, while additional diseases and health costs are reduced.[6] In addition, thanks to self-management support interventions, individuals are given autonomy and

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unnecessary hospital admissions are eliminated.[7] Since a certain point of view will not suit everyone, self-management support should be adapted to individual needs and circumstances.[6] In order for individuals to fulfill the responsibilities for their health after transplantation and to improve their self-management, motivational interviews conducted in a patient-centered manner can be utilized to stimulate a sense of change. Motivational Interviewing (MI) is a patient-centered approach that is used to reveal behavioral changes in individuals.[8] The effectiveness of MI was shown in patients with type II diabetes mellitus.[9] and cesarean section in pregnant women.[10] In this technique, the reasons for the changes are revealed without telling what people will do and why they need to act in that way.[11] A consultant may provide guidance by providing information to an individual; however, the individual decides how to proceed. They should keep having exchanges, trying to understand the world from the patient's point of view (accurate empathy), and the strengths and efforts of the patient (affirmation).[12] They should also talk about individuals' feelings and the way their experiences affect their beliefs and expectations. Changes can be achieved by individual motivation, rather than information and guidance.[13] MI is known to be effective in achieving adaptation to chronic diseases and creating positive behavioral changes. In addition, it is emphasized that it can improve the patient-consultant relationship and contribute to patient satisfaction.[14] A trusting relationship is an important requirement for the cooperation and participation of kidney transplant recipients in the joint decision-making process in carrying out their self-management.[6] Trusting relationship-based MI sessions helps patients strengthen their self-management.[15] Kidney transplant recipients improving their self-management by creating their own change strategies through MI sessions can make use of MI sessions in terms of adapting to a new lifestyle after transplantation as well as preventing unwanted conditions and improving health outcomes. However, there have been no studies have been conducted on the effect of MI on adult kidney transplant recipients.

Material and Methods

Aims

The present study aims to examine the effects of Motivational Interview sessions on self-management that will be conducted in accordance with the post-discharge requirements of adult kidney transplant recipients.

The hypotheses are as follows:

H1-1: Treatment adherence of adult kidney transplant recipients who receive motivational interview-based counseling is significantly different from the control group.

H1-2: Medication adherence of adult kidney transplant recipients who receive motivational interview-based counseling is significantly different from the control group.

H1-3: GFR of adult kidney transplant recipients who receive motivational interview-based counseling is significantly different from the control group.

H1-4: Serum creatinine levels of adult kidney transplant recipients who receive motivational interview-based counseling are significantly different from the control group.

Design/Methodology

This study protocol defines a single-center, single-blind, and evaluator-blinded, parallel-group Randomized Controlled Trial (ratio of 1:1) design conducted at the transplant outpatient clinic of a hospital in Antalya/Turkey. In the study, Standard Protocol Items: Recommendations for Interventional Trials-SPIRIT (2013) [Supplementary File 1][16,17] and CONSORT 2010 (Consolidated Standards of Reporting Trials) have been used.[18,19] The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) figure with design and outcome assessments, taken from the EQUATOR Network is shown in Table 1. ClinicalTrials.gov registration has been obtained (NCT04956406) on July 2021. ClinicalTrials.gov registration has been obtained on July 2021. The study will be conducted in the transplant outpatient clinic of a hospital between 2021 and 2022. The groups will be allocated by randomizing the intervention (motivational interviewing) and the control group (routine care). The researcher is not blinded. First, pre-tests will be performed, followed by a post-test after 1 month and a follow-up test after 3 months. The sample size has statistically been determined using Power Analysis, which has been calculated to include 32 individuals in the control and 32 in the intervention group, via eta-squared = 0.05 (representing a medium effect size), an alpha level of 5%, and power level of 95%, will be consisted of a total of 80 people, that of 40 in the control group and 40 in the intervention group, considering the missing data.

Study framework

The framework of the study will be created in accordance with the population, intervention, comparison, outcomes, and study type (PICOS) criteria. According to this; our population will be adult kidney transplant recipients, our intervention will be motivational interviewing, our comparison group will be routine care, our outcome will be self-management, and our study design will be a randomized controlled trial. The inclusion criteria of the study will be volunteering to participate in the

Table 1: Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) figure with design and outcome assessments

	PHASES						
Time point**	**Recording**	**Allocation**	**Post-allocation**				**Finish**
	Patients' arrival for outpatient follow-up (-T1)	**10 min before MI (T0)**	**1. MI (T_1)**	**2. MI (T_2)**	**3. MI (T_3)**	**1 months later (T_4)**	**3 months later (T_5)**
RECORDING:							
Eligibility Screening	X						
Informed Consent	X						
(List of other transactions)							
Allocation		X					
INTERVENTIONS:							
[Intervention]							
[Control]			X			X	X
EVALUATION:							
Demographics and Patients' characteristics		X				X	X
Scales (Self-management, VAS, self-care agency)		X				X	X
Creatinine		X				X	X
GFR		X				X	X

study, being aged ≥18 years, being in the 3-6 months after kidney transplant, speaking, reading, and writing in Turkish, and having a mobile phone. The exclusion criterion will be requesting to withdraw from the study, and the removing criterion will be the development of rejection.

Randomization and allocation

In the research, "stratified simple randomization" will be performed to create an equal number of samples for the intervention and control groups using pre-test, post-test, and control group design. The balance will be achieved between the groups via this method. After the determination of the stratum consisting of 3rd, 4th, 5th, and 6th months after kidney transplantation, 20 individuals will be distributed via https://www.randomizer.org/. According to the randomization results, a list will be created for those who will be included in the intervention and control groups. The randomization will be performed by the researcher and the numbers in the list will be placed in envelopes. The CONSORT flow diagram of the participants is shown in Figure 1.

The sample of the research study will consist of two groups:
1. Motivational interview (Intervention) group:
2. Routine care (Control) group:

Motivational interviews will be conducted by a researcher who has taken education about it.

Blinding design

The research is single-blind. Because of the nature of the intervention, only participants were blinded, and informed consent was appropriately designed. Since the researcher will perform the sessions, she will not be blinded. In order to prevent evaluation bias, the researcher will blind the statistician through a data file that does not explicitly specify the intervention or control group.

Interventions

MI is a patient-centered referral approach used to identify behavioral changes that will help patients notice and analyze their feelings of ambivalence. The methods include open-ended questions, reflective listening, summarizing, affirmations, and change talk. During change talk, it is important to ask clarifying questions, ensure decisional balance, consider the future, and reveal goals and values. It is known that 15 minutes of interviews are effective.[20] Motivational interview intervention will be applied to adult kidney transplant recipients. Interviews will be conducted with the intervention group during 3-6 months after the transplantation lasting between 15 to 30 minutes with ten-day intervals three times. The first session will be conducted face-to-face at the transplant center, and the second and third sessions will be phone interviews. Prior to the start of the study, 6 recipients were interviewed for pilot implementation. Among recipients within at least 3 months of transplantation, the issues they struggle with and want to talk about were weight gain, salt consumption, smoking, high cholesterol, hypertension, DM, and exercise. Thus, open-ended questions have been created about these topics in a semi-structured interview form. The interventions will be implemented by Erdem according to the protocol established by Erdem and Cebeci. The researcher will select patients in the existing appointment list with stratified simple randomization created via randomizer.org. After the selected patient is informed about the study and their consent is obtained, interviews will be held in the interview room at the clinic. Interviews will be held in the late afternoon of that

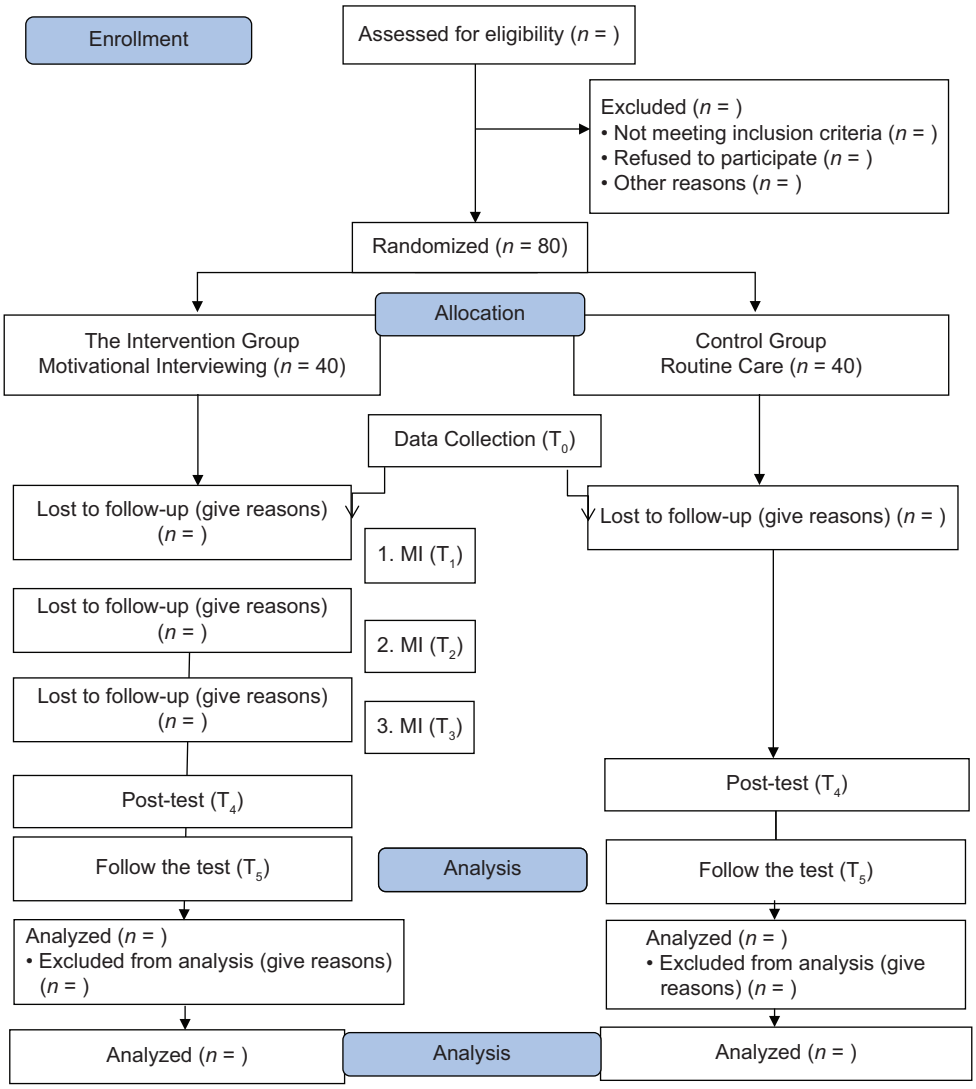

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram of participants

day and consent will be obtained in the morning. The reason why interviews are held in the afternoon is that individuals give a blood samples for tests, get examined, and then have breakfast to take medications. In case individuals in the intervention group are hospitalized or rejection develops, they will be excluded from the study. The second and third phases of the interview will be performed via phone on scheduled days according to participants' availability. The control group will be provided with routine face-to-face care (standard training) by a nurse educator at the transplant center. It is considered that there is no infection between the intervention and control group since the clinic allows a certain number of patients at one time, they wait for their turn maintaining social distancing, and one or two patients will be interviewed in a day according to inclusion criteria.

The post-tests will be performed after one month for both groups. Additionally, evaluations will be conducted with a 3-month follow-up test. If patients need to consult units such as endocrine and dietitian, there is no harm in research.

Outcome measures

Socio-demographic data and patient information form (age, gender, educational status, marital status, occupational status, income, smoking status, regular exercise status, alcohol consumption, transplantation date, donor type, concomitant disease, Cr and GFR levels, the level of adherence to immunosuppressive drugs, re-hospitalization status and reason) will be used. In the next phase, prior to the first MI, various scales will be used in a pre-test, and then in the post-test and follow-up tests.

Primary outcome measure

Self-management scale

The self-management scale is the first scale to be applied as a preliminary test in kidney transplant recipients.[21]

Turkish version of the 4-point Likert scale includes 13 items. Scale items are scored as 1"never applied", 2 "applied slightly", 3 "applied very often" and 4 "fully applied". The calculation is recommended to be performed based on the item mean scores rather than an overall mean. The lowest possible score obtained from each item and subscale is 1 while the highest possible score is 4. The scale has no cutoff points and reversed items.[22] [Time Frame: Change from Baseline Self-Management at 3 months].

VAS for medication adherence

Medication adherence will be evaluated with self-reported VAS ranges from 0 to 100.[23] Rating will be 0 "taken no medications" to 100 "taken medications perfectly". A score different from 100 will be considered a non-adherence [Time Frame: Change from Baseline VAS for Medication Adherence at 3 months]

VAS for self-care

The rating will be between 0 and 100. 0: "I can't provide my own care".100: "I am able to provide my own care". [Time Frame: Change from Baseline VAS for self-care at 3 months].

Secondary outcome measure

Glomerular filtration rate (GFR)

Official measurements performed by the hospital [Time Frame: Change from Baseline GFR at 3 months].

Serum creatinine

Official measurements performed by the hospital [Time Frame: Change from Baseline Serum Creatinine at 3 months].

Data collection procedure

In this study, the data will be collected at five different times prior to the MI, after MI three times at 10 days intervals, and three months after the first interview for a follow-up test. The details and timing of data collection are shown in Table 1.

Prior to MI (T_0): The first researcher will evaluate socio-demographics and patient information form, Self-Management on Kidney Transplant Recipients Scale, VAS for medication adherence, and self-care evaluation (self-management) using a visual scale and patient outcomes.

1st MI (T_1): The interview will be conducted in the interview room using a semi-structured motivational interview form.

2nd MI (T_2): 2nd interview will be held over the phone 10 days after the first session.

3rd MI (T_3): 3rd interview will be held on the phone 10 days after the second session.

1 month later (T_4): 1 month after the first interview, the first researcher will evaluate socio-demographics and patient information form, Self-Management on Kidney Transplant Recipients Scale, VAS for medication adherence, self-care evaluation (self-management) using a visual scale and patient outcomes.

3 months later (T_5): 3 months after the first interview, the first researcher will evaluate socio-demographics and patient information form, Self-Management on Kidney Transplant Recipients Scale, VAS for medication adherence, self-care evaluation (self-management) using a visual scale and patient outcomes.

Ethical considerations

The research was conducted within the framework of the Declaration of Helsinki. Written informed consent was obtained from the participants before starting the research. Written approval was obtained from the Clinical Research Ethics Committee of the university (Date: 08/04/2020, Number: KAEK-283). Written permission was obtained from the Hospital, and authors' permission was received via email. Data was not shared; results can be viewed via publication.

Data analysis

The Self-Management on Kidney Transplant Recipients Scale, VAS, and patient outcomes (medications, kidney function, re-hospitalization, history of chronic diseases such as HT and DM, infection, active complaint) will be used. In addition to descriptive statistical methods (mean, standard deviation, median, frequency, ratio, minimum, maximum), Student's *t*-test will be used for the comparison of two groups of normally distributed variables and the Mann-Whitney U test will be used for non-normally distributed variables parameters when comparing quantitative data. Paired Samples test will be used for inter-group comparisons of normally distributed variables. The Wilcoxon Signed-Rank test will be used for inter-group comparisons of non-normally distributed variables. For missing data, the two best methods, multiple imputations, and maximum likelihood imputation will be used. An intention-to-treat analysis (ITT) will be performed to maintain the effect of randomization and to prevent attrition bias.

Discussion

After transplantation, patients need lifelong follow-up. Repetitive patient training provided by nurses can be an important factor in making behavioral changes through monitoring and self-management while improving the quality of life of these patients.[24] Kidney transplant recipients want to participate in the decision-making process and be collaborative. It has been reported that

this situation is especially important in the first year after transplantation. However, self-management support should be adapted to individual needs and conditions.[6] Motivational interviewing reveals the feeling of change by enabling individuals to reach their inner motivations about the issues they struggle with during their lifelong monitoring. This article describes the protocol of a single-center single-blind, randomized controlled trial to determine the effect of motivational interviewing on self-management behaviors in kidney transplant recipients. There is a lack of scientific evidence about self-management behaviors in kidney transplant recipients through motivational interviewing. It is considered that this make a significant contribution with this study to the literature in terms of providing evidence for the effects of motivational interviews on self-management behaviors in kidney transplant recipients.

Limitations

Since the researcher is also the interviewer, she cannot be blinded. The study is single-center and will be conducted only with kidney transplant recipients.

Conclusion

Individuals who have had a transplant after kidney failure may consider it as a chance given to them. This point of view can ensure that they strictly follow the recommendations in the first months. However, as they get used to the process, some situations may be ignored or they may struggle to follow up. In this case, it is necessary to activate the sense of change in individuals to help them maintain healthy transplantation and be in a better situation. Motivational interviews are one of the methods that are often recently recommended in the management of chronic diseases.[9,11-13] However, no study has been found on motivational interview and techniques in kidney transplant recipients. In this respect, the paper is unique. Motivational Interviewing techniques can be recommended to use as a health policy. The results of this study guide healthcare professionals to the practice effective Motivational Interviewing techniques in kidney transplant recipients to maintain a healthy transplant.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Supplementary File 1

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

Supplementary File 1: 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	_____2,3_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	____2_____
	2b	All items from the World Health Organization Trial Registration Data Set	_____2_____
Protocol version	3	Date and version identifier	_____2_____
Funding	4	Sources and types of financial, material, and other support	____ Title page _
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_Title page_____
	5b	Name and contact information for the trial sponsor	_Title page _
	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	___Title page _
	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)	_____NONE_____
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	_____3_____
	6b	Explanation for choice of comparators	_____3_____
Objectives	7	Specific objectives or hypotheses	_____2_____
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)	____3_____
		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	_____2,3_____
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)	_____3_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	_____3,4_____
	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)	___3,4_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_____3,4_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_____3,4_____

Contd...

Supplementary File 1: Contd...

Section/item	Item No	Description	Addressed on page number
		Methods: Participants, interventions, and outcomes	
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	4,5
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
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	4
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	3,4
		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	3
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	3
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	3
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	3
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	4
		Methods: Data collection, manageent, 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	4
	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	4
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	NONE
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	5
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NONE
	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)	5

Contd...

Supplementary File 1: Contd...

Section/item	Item No	Description	Addressed on page number
		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	____NONE_____
	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	_____NONE_____
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	_____NONE_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_____6_____
		Ethics and dissemination	
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	____5_____
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)	_____5_____
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_____5_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____NONE_____
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	_____5_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	__Title Page__
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	_____NONE___
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	____5_____
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	_____5_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_Title Page__
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____5_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	___NONE_____
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	_____NONE_____

*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