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Protocol for a pilot randomised controlled trial: A brief self-compassion intervention for adolescents with type 1 diabetes and disordered eating

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Abstract

Introduction: Adolescents with type 1 diabetes are at a higher risk of developing psychiatric disorders, particularly eating disorders, compared to their healthy peers. In turn, this increases the risk for sub-optimal glycaemic control and life-threatening diabetes-related complications. Despite these increased risks, standard diabetes care does not routinely provide psychological support to help prevent or reduce mental health risks. There is an urgent need to develop 'clinically usable' psychosocial interventions, that are acceptable to patients and can be realistically integrated into clinical care. This study aims to examine the feasibility and acceptability of a brief self-compassion intervention for adolescents with type 1 diabetes and disordered eating behaviour.

Methods and analysis: This pilot randomised controlled trial (RCT) will examine the effectiveness of a brief self-compassion intervention, compared to a waitlist control group. Participants aged 12-16 years will be recruited from three diabetes outpatient clinics in Auckland, New Zealand. The brief self-compassion intervention is adapted from the standardised 'Making Friends with Yourself' (MFY) intervention and will be delivered in a group format over two sessions. As well as examining feasibility and acceptability through the flow of participants through the study and qualitative questions, we will assess changes to disordered eating behaviour (primary outcome), self-care behaviours, diabetes-related distress, self-compassion, stress and glycaemic control (secondary outcomes). Such data will be used to calculate the required sample size for a fully powered RCT.

Ethics and dissemination: The current trial has received ethics approval from the Health and Disability Ethics Committee (HDEC; research project number A+8467). Study results will be disseminated through peer-reviewed journals and conferences.

Trial registration number: ANZCTR (12619000541101).

Strengths and Limitations:

- There is an urgent need to develop 'clinically usable' interventions in diabetes care
- Self-compassion may offer an effective method to improve psychological health and self-management among adolescents with type 1 diabetes
- The pilot randomised controlled trial will evaluate the feasibility, acceptability and short-term efficacy of the brief self-compassion intervention in 28 teenagers with type 1 diabetes
- The study will inform a larger, multi-centred, fully-powered, randomised controlled trial, with the aim of implementing an effective and clinically usable intervention into standard diabetes care

Introduction

This protocol paper describes a pilot RCT designed to evaluate the feasibility, acceptability, and short-term efficacy of a brief self-compassion intervention for adolescents with type 1 diabetes (T1D) and disordered eating behaviours. Adolescents with T1D face the dual challenge of learning how to manage their chronic condition while concurrently dealing with what can be normatively difficult developmental changes. Maintaining optimal self-management of T1D requires adherence to a complicated routine of daily self-administration of insulin and monitoring diet, energy expenditure and blood glucose levels (1). Adolescents must learn how to make these complex routines flexible enough to implement into their daily life including school, hobbies and other activities (2). Unsurprisingly, diabetes self-management tends to deteriorate during adolescence, with adolescents showing sub-optimal glycaemic control and higher rates of complications compared to adults or younger children (3).

Adolescents with T1D also show much greater rates of psychological disorders, especially eating disorders, than their healthy peers (4, 5). In a recent national Australian study of adolescents with T1D, 50% of female and 18% of male adolescents scored over the cut-off for disordered eating behaviour (6). Eating disorders have also been shown to be twice as common in adolescent females with T1D compared to their healthy peers (7) and rates of disordered eating in adolescents with T1D are rising (8, 9). Given that behaviours such as insulin omission and purging are associated with increases in diabetes-related complications (6, 10), this is concerning. Poor psychological health, including disordered eating, has the potential to make daily self-management decisions even more challenging and has known associations with lower rates of glucose testing and insulin adherence (11), poorer glycaemic control (12) and more frequent hospitalisations and complications (13). Therefore,

prioritising psychological health and wellbeing is an essential component of successful diabetes care and may be even more relevant during adolescence.

Despite the high prevalence of mental health disorders among adolescents with T1D, treatment options are limited. Current interventions to target psychological issues include psychopharmacology (such as antidepressants) and psychosocial interventions. Research has shown that individual and group-based interventions focused on improving family relationships, stress management, and coping skills can improve adherence, glycaemic control and quality of life (14). However, such interventions are rarely incorporated into standard diabetes care due to funding constraints and a lack of therapist availability (15, 16), as well as the logistical issues associated with family therapies. Furthermore, only one study has examined the use of an intervention specifically targeting disordered eating behaviour in adolescents with T1D (17). There is thus a strong need to develop interventions to treat psychological distress, especially disordered eating behaviour, that are acceptable to adolescents with T1D and can be realistically incorporated into routine clinical care.

Self-compassion is an emerging approach which may offer an effective method to improve psychological health and self-management among adolescents with T1D. Self-compassion appears highly relevant to the self-criticisms that commonly arise following difficulty adhering to complex self-management regimens. At its core, self-compassion is characterised by: (1) being aware of one's moment to moment experiences with a sense of emotional balance and non-judgement (mindfulness), (2) acknowledging that suffering and imperfection are part of being human (common humanity), and (3) taking an active role in being caring and understanding toward oneself (self-kindness) (18). Lower self-compassion has been closely linked to greater depression and anxiety (19), including in adults with diabetes (20, 21), while higher self-compassion is associated with less rumination, self-criticism, perfectionism, and fear of failure (18, 22). Self-compassion has demonstrated

benefits for those with chronic illnesses (including inflammatory bowel disease and arthritis), such as improved self-management and coping (23). Most recently, a standardised 8-week self-compassion programme for adolescents, 'Making Friends with Yourself' (MFY), adapted from the Mindful Self-Compassion (MSC) Program for adults (24), showed significant improvements in self-compassion, life satisfaction and depression, compared to a waitlist control group, in healthy adolescents (23). Mindfulness, social connectedness, anxiety, stress, resilience, curiosity and gratitude have also been shown to increase throughout the MFY programme (25, 26).

To date, MFY has not been trialled in adolescents with diabetes or any other chronic illness. However, a recent RCT compared the 8-week MSC Programme for adults with diabetes to a waitlist control group (21). Researchers found increased self-compassion was associated with reductions in diabetes-related distress, depression, and improvements in glycaemic control, both at post-intervention and at the 3-month follow-up compared to the waitlist control group.

Considering the vital role psychological health plays in diabetes-related outcomes (27) and the conceptual fit between the purpose of self-compassion training and the issues confronting adolescents with T1D, we developed a brief (2-session) self-compassion intervention targeted to adolescents with T1D and disordered eating behaviour. The current study will examine the programme's feasibility and acceptability for adolescents with T1D and provide estimates of change in psychological and physical health outcomes. It is hypothesised that the brief self-compassion intervention will improve disordered eating behaviours, self-care behaviours, diabetes-related distress, self-compassion, stress and glycaemic control, compared to the waitlist control group at post-intervention.

Methods and analysis

Design overview

The study is a pilot RCT of a brief self-compassion intervention (treatment group), compared to a waitlist control group, in 28 adolescents with T1D. The study will be conducted in accordance to the CONSORT guidelines (28) and has been prospectively registered in the Australian New Zealand Clinical Trials Registry (ANZCTR 12619000541101). The SPIRIT recommendations were adhered to in reporting the protocol (29).

Participants

Participants in the study are adolescents with T1D who are currently being recruited from three paediatric and adolescent diabetes clinics in Auckland, New Zealand. Adolescents are eligible for inclusion in the study if they meet the following criteria: (1) are aged 12 to 16 years, (2) diagnosed with T1D more than 6 months ago at time of recruitment and (3) demonstrate moderate to high instances of disordered eating behaviour on the Diabetes Eating Problem Survey Revised (DEPS-R) (30) screening tool. A moderate to high disordered eating behaviour cut-off score was chosen to allow more room to detect changes and to offer the interventions to those at the highest risk. Exclusion criteria includes: (1) non-English speaking adolescents, (2) adolescents with developmental disorders (e.g. Autism Spectrum Disorder) and (3) adolescents diagnosed with a serious mental disorder requiring ongoing treatment (e.g., psychosis). See Figure 1 for an overview of the proposed flow of participants through the study.

Sample size calculation

Based on other studies suggesting the prevalence of disordered eating of 27% for boys and 42% for girls in T1D (31), we estimated that we would need to screen approximately 50 adolescents to enroll at least 20 adolescents (who score over the cut-off on the DEPS-R) for the pilot study. We will use the observed changes in psychological outcomes (e.g., DEPS-R)

and physical health outcomes to calculate the required sample size for a subsequent fully powered RCT.

Intervention development

The brief self-compassion intervention was adapted from the 8-week MFY programme (25), in consultation with Karen Bluth and five other trained MFY and MSC teachers. Components from the MFY programme were chosen for the brief adaption because they are: (1) foundational exercises covering the basics of mindfulness and self-compassion and (2) address body image concerns and feelings of isolation, which have been highlighted in the literature to be relevant to adolescents with T1D (32). These components included group exercises and discussions, topics, art activities, meditations and individual reflection exercises (see Table 1).

Brief self-compassion intervention

The brief self-compassion intervention will involve two 2-hour sessions conducted at the University of Auckland. The intervention sessions will be facilitated by the first author (A.B), a trained MFY teacher.

As summarised in Table 1, Session 1 will focus on giving participants an understanding of mindfulness through several tangible activities including a mindful movement activity, group discussions and a mindful activity using a stone or shell. Psychoeducation around adolescent brain development and emotion regulation systems (33) will be taught to help to establish the reasons why mindfulness and self-compassion can help with managing stress, especially in adolescence. Regarding self-compassion, the 'How Would I Treat a Friend' exercise offers an interactive method of explaining self-compassion before practicing the self-compassion coping skills of 'Comforting Gesture' (i.e. 'Soothing Touch') and the 'Three Steps of Self-Compassion' (i.e. 'A Moment for Me'). The 'How Would I Treat a Friend' exercise shows adolescents that they often treat themselves much

more harshly than they treat their friends through exploring their reactions to how they would treat themselves versus their friends in difficult situations, such as receiving a bad mark on an important test. Finding a 'Comforting Gesture' (such as holding your hands over your heart or stomach), involves practicing applying self-compassion to soothe and regulate emotions during stressful situations in one's life. The 'Three Steps of Self-Compassion' involves applying the three elements of self-compassion (mindfulness, common humanity and self-kindness) to cope with difficult emotions.

Session 2 is focused on developing coping skills to deal with body image concerns and feelings of isolation. Opening with a loving-kindness meditation will provide a reminder of the concept of self-compassion and the 'Comforting Gesture' tool from Session 1 before summarising the content taught in the last session. Self-esteem versus self-compassion and the cost of social comparison is then discussed to help teens understand how comparing themselves to others can create suffering and to allow them to practice using the coping skills taught in Session 1 when they experience feelings of inadequacy. The 'Crossing the Line' group activity then emphasises the common humanity element of self-compassion by asking adolescents to cross a line of string if they have experienced certain feelings or situations, such as feelings of isolation, been bullied or having compared themselves to their friends or an image in the media. Adolescents will then practice a compassionate body scan meditation and writing themselves a compassionate letter as further skills to use surrounding body image concerns.

Handbooks will be given to participants to review topics and outline the coping skills taught in the sessions, with examples of situations where it may be helpful to use them. Recordings of the meditations used in the sessions will also be emailed to the participant's parent/ caregiver and the participant.

Study procedure

The study started recruitment on the 24th of May 2019 and is estimated to finish in late October 2019. Figure 1 depicts the flow of participants through the trial. Eligible families will be invited by diabetes nurse educators at their Paediatric Diabetes Service clinic appointments to participate in a study investigating body image concerns in adolescents with T1D. Interested participants will be referred to the first author (A.B), who will verbally explain the study to interested families. Once consent/ assent is given, the adolescents will complete the DEPS-R screening tool. Participants who score over the cut-off score for moderate disordered eating behaviour, will then be randomised to either the treatment group or a waitlist control group (who will receive the intervention after the treatment group has completed post-intervention measures) on a 1:1 basis. Randomisation will occur via sealed envelopes labelled with sequential study numbers, prepared by a biostatistician independent of the study.

After randomisation, participants will also complete standardised questionnaires measuring self-care behaviours, diabetes-related distress, self-compassion and stress in clinic or online. After completing the intervention, participants will be given the same questionnaires as well as open-ended questions to assess the acceptability and feasibility of the programme. Participants in the waitlist control will then start the intervention.

Outcome measures

The primary goal of this pilot study is to determine the feasibility and acceptability of the brief self-compassion intervention in the service of designing a larger, multi-centred, powered study. This will be assessed by evaluating whether adolescents with T1D are willing to participate in the intervention (i.e. recruitment and uptake), reasons for not wanting to participate, the acceptability of the delivered intervention (assessed via qualitative questions), study attrition rate and the suitability of the outcome measures. Qualitative data, through

questionnaires at post-intervention, will also be used to refine the intervention content and comment on strengths and weaknesses of the program.

In addition, the following psychological and physical health outcomes will be assessed to give preliminary estimates of the study's efficacy and to estimate the sample size needed for a fully-powered RCT:

1. Disordered eating behaviour as measured by the Diabetes Eating Problem Survey Revised (DEPS-R) (30). The DEPS-R is a 16-item diabetes-specific self-report measure of disordered eating. Participants are asked how true each item is for them (e.g., 'I feel fat when I take all of my insulin') on a 6-point Likert scale (0=never to 6=always), with items summed to produce a total score. The scale has demonstrated good reliability (α=0.86-0.91) and validity in adolescents with diabetes samples (30, 34, 35). For the current study, the moderate disordered eating cut-off (≥10) for inclusion in the study will be used. DEPS-R results for all adolescents screened for eligibility will be reported to give an indication of prevalence of moderate disordered eating behaviour in the Pediatric Diabetes clinics.
2. Self-care behaviours as measured by the Self Care Inventory-Revised Version (SCI-R) (36). The SCI-R is a 15-item questionnaire which assesses how often diabetes self-care behaviours have been adhered to over the past one to two months on a 5-point Likert scale (1=never to 5=always). The self-care behaviours assessed include the main components of the type 1 diabetes self-management routine such as monitoring and recording glucose levels, administering and adjusting insulin and regulating meals and exercise. Items will be averaged and converted to a 0-100-point scale to produce a total score, with higher values

representing better self-care. The scale has shown good reliability (α=0.77-0.78) and validity (37, 38).

3. Diabetes-related distress as measured by Problem Areas in Diabetes Survey (PAID) (39). The 20-item questionnaire lists common negative emotions related to living with diabetes such as, 'feeling alone with diabetes', and 'worrying about the future and the possibility of serious complications'. The 20-items are measured on a 6-point Likert scale (1=not a problem to 6=a serious problem), with items averaged to produce a total score. The scale demonstrates good reliability (α=0.93) and validity (40).
4. Self-compassion as measured by the Self-Compassion Scale, short form (SCS-SF) (41). The 12 items are measured on a 5-point Likert scale (1=almost never to 5=almost always), with items averaged to create a total score. Example items include: 'when I fail at something important to me I become consumed by feelings of inadequacy' and 'when I'm feeling down I tend to obsess and fixate on everything that's wrong'. Reliability for this scale is good with a Cronbach alpha of α = 0.77-.79 (25, 26) in adolescent samples. Strong predictive, convergent and discriminant validity has also been demonstrated (42, 43).
5. Stress as measured by the Perceived Stress Scale (PSS) (44). The questionnaire assesses feelings of stress, hassles and coping during the past month. For example, 'in the last month, how often have you felt that you were unable to control the important things in your life?'. The 14-items are measured on a 5-point Likert scale (0=never to 4=very often), with the score of each item combined to produce a total score. The scale has been shown to associate with glycaemic control (45) and demonstrates good reliability (α=0.75-.88) and validity (46).

6. Glycaemic control as measured by Glycosylated haemoglobin (HbA_{1C}). HbA_{1C} is a blood test collected during routine outpatient appointments (which occur every 3-4 months), which is a reliable measure of blood glucose control over a period of 3-4 months. HbA_{1C} is measured in millimoles per mol (mmol/mol), with lower values indicating better glycaemic control (47). HbA_{1C} ranges from 31 to 108 mmol/mol, with the ideal target for all child and adolescent age groups being below 58 mmol/mol (1). HbA_{1C} levels will be accessed from clinical records at baseline and post-intervention (window of 12-16 weeks after baseline).

Data analysis plan

Descriptive statistics will be reported for proportion of adolescents who were screened and who scored over the cut-off for the DEPS-R, rates of disordered eating across all adolescents screened, number of adolescents who attended the sessions, and number of adolescents who dropped out of the study. Data will be tested for violations of statistical assumptions. Means, standard deviations and 95% confidence intervals will be reported with the analyses. An independent samples t-tests will be conducted at post-intervention (see time 2, Figure 1) to test our hypothesis for differences between the intervention group and waitlist control group in disordered eating behaviour, diabetes-related distress, stress, self-care behaviours and self-compassion. An independent samples t-test will also be conducted at the 12-week follow-up to assess any possible differences between groups for glycaemic control. In addition, to increase sample size and statistical power, an exploratory analysis will combine post-intervention data from participants in the treatment group (at time 2) and participants in the waitlist control group (at time 3) to examine within and between group changes from baseline, using paired samples t-tests. An intention to treat analysis is planned.

Patient and Public Involvement

Patients, carers and members of the public were not involved in the study design phases of the current study. However, during the recruitment process patients who CHOOSE not to participate will be asked to assess whether the time commitment or required travel was a reason for not choosing to participate, when possible. In addition, patients who are participants PARTICIPATE in the sessions will also provide qualitative feedback on the burden of participating, the recruitment process and the format and content of the sessions to inform the future RCT. Regarding dissemination of results, during recruitment we ask patients whether they consent to the findings being disseminated via peer reviewed journal articles and conferences. We also ask whether they would like to be informed of the results at the end of the study and how (e.g. email/post). Patients who agree to being informed of the study results are sent a letter with the key findings and any publications arising from the study. In some cases, patients may also be invited to a departmental presentation of the study findings.

Ethics and dissemination

The study was approved by the Health and Disability Ethics Committee (HDEC; research project number A+8467). Due to screening for and only including adolescents with disordered eating behaviour, it was recommended to include a waitlist control group (rather than a standard care control group) in order to offer all eligible participants the intervention. Participants who report significant psychological concerns, such as self-harm, or issues relating to their diabetes that fall outside of the scope of the intervention, such as complex self-management concerns, will be referred to the diabetes team psychologist. The paediatric and adolescent diabetes team (including endocrinologists, diabetes nurse educators, dieticians and a psychologist) will provide study support throughout the trial, including monitoring any adverse events. Study results will be disseminated through peer-reviewed journals, a doctoral thesis, and conference presentations.

Discussion

To our knowledge, the current study will be the first to assess the acceptability of self-compassion intervention for adolescents with T1D and examine the feasibility of a brief adaption of the MFY programme. The intervention addresses the rising concern of disordered eating in adolescents with T1D (8, 9), building on the sparse literature in this area (17). The intervention will aim to teach adolescents evidence-based mindfulness and self-compassion skills to help them cope with stress, difficult emotions, self-management obstacles, and body image concerns and to determine whether self-compassion is a feasible and acceptable approach. As the prevalence and impact of these psychological concerns in adolescents with T1D is a current obstacle in diabetes care, the study will help determine whether self-compassion is a feasible and acceptable approach.

The novelty of testing self-compassion for adolescents with T1D and the brief format of the intervention are key strengths of this study. Firstly, although self-compassion has previously demonstrated efficacy in adults with diabetes (21) we believe it may be even more beneficial for adolescents with T1D. Adolescence is a period of vulnerability with an increased risk for self-criticism, poor self-esteem, and body image concerns (48). In adolescents with T1D these concerns are exacerbated by difficult self-management routines and parental conflict surrounding their diabetes-care (49), as well as increased risk of psychological distress and feelings of isolation (32). Self-compassion may encourage adolescents to be more accepting and kind to themselves when facing these issues, without engaging in problematic or counterproductive self-criticism. The common humanity aspect of self-compassion is likely to help validate feelings that emerge from any struggles they are experiencing, such as feelings of isolation, feeling less than, stress and sadness, as normal and common to all teens.

An adapted version of the 'Making Friends with Yourself' programme to a brief (2-session format) was chosen to address the lack of of 'clinically usable' interventions in diabetes care. Although it is widely acknowledged that psychological care is a key component of improving health outcomes in diabetes (16, 27), the integration of psychosocial care into routine diabetes care remains lacking. Despite the growing literature demonstrating the efficacy of psychosocial interventions for improving psychological outcomes in T1D, interventions are rarely designed with the intention of being 'clinically usable' and in a format that could potentially be adopted into standard care.

Altogether, our aim is to examine the feasibility and acceptability of a brief self-compassion intervention, as well as provide estimates of short-term efficacy. If the brief self-compassion intervention is found to be feasible and acceptable to adolescents, future plans include conducting a fully powered RCT to examine the long-term efficacy of the intervention, with the intention of developing a clinically usable psychosocial intervention for youth with both T1D and disordered eating behaviours.

Authors contributions: A.B, P.H and A.S came up with the conception and design of the study. A.B will be recruiting participants and conducting the program sessions. K.B provided training and consultation during the program development phase and will provide A.B with supervision throughout the sessions. A.B. and A.S. wrote the manuscript. N.S., P.H and K.B reviewed and edited the manuscript.

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Figure 1: Flow of participants through the study

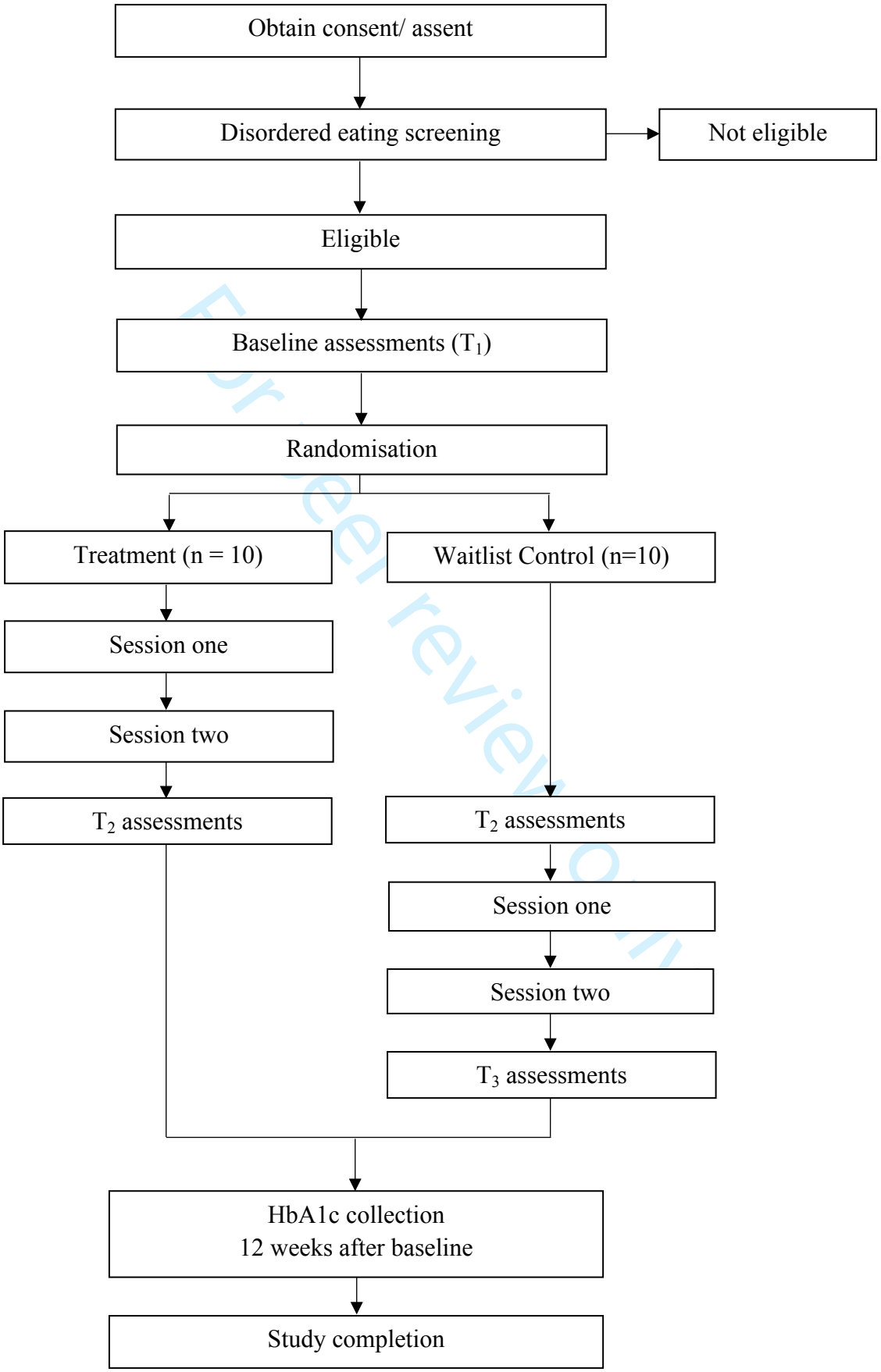

Table 1: Key Exercises and Educational Components of the Brief Self-Compassion Intervention for Adolescents

Session one	Session two
Topic: what is self-compassion?	Meditation: Loving kindness meditation
Mindful movement activity: stop and be meditation	Topic: Summary of last week's content
Topic: mindfulness and the wandering mind	Topic: self-esteems vs. self-compassion
Mindful observation activity: here-and-now stone	Discussion: the cost of social comparison
Topic: the adolescent brain	Meditation: Compassionate body scan
Self-compassion exercise: how would I treat a friend?	Group exercise: crossing the line
Self-compassion exercise: comforting gesture	Compassionate letter
Self-compassion exercise: three steps of self-compassion	
Meditation: music meditation	

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

Section/item	Item No	Description	Page Number, on which item is reported
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	p.1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	p.2
	2b	All items from the World Health Organization Trial Registration Data Set	na
Protocol version	3	Date and version identifier	p.1
Funding	4	Sources and types of financial, material, and other support	p.17
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	p.1 & 17
	5b	Name and contact information for the trial sponsor	na
	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	na
	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)	na
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	p.4-6
	6b	Explanation for choice of comparators	p.14
Objectives	7	Specific objectives or hypotheses	p.6
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)	p.7
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	p.7
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)	p.7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	p.8-9
	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)	p.14
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	na
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	na
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	p.10-13

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)	p.21
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	p.7
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	na
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	p.10
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	p.10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	p.10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	na
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	na
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	p.10-13

	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	na
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	na
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	p. 13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	p.13
	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)	p.13
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	na
	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	na
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	p. 14
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	na
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	p.14
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)	p.7
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	p.10
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	na
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	na
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	p.16
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	na
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	p.14
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	p.14
	31b	Authorship eligibility guidelines and any intended use of professional writers	p.17
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	na
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	na

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	na

BMJ Open

Protocol for a feasibility study: A brief self-compassion intervention for adolescents with type 1 diabetes and disordered eating

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Protocol for a feasibility study: A brief self-compassion intervention for adolescents with type 1 diabetes and disordered eating

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Abstract

Introduction: Adolescents with type 1 diabetes are at a higher risk of developing psychiatric disorders, particularly eating disorders, compared to their healthy peers. In turn, this increases the risk for sub-optimal glycaemic control and life-threatening diabetes-related complications. Despite these increased risks, standard diabetes care does not routinely provide psychological support to help prevent or reduce mental health risks. There is an urgent need to develop 'clinically usable' psychosocial interventions, that are acceptable to patients and can be realistically integrated into clinical care. This study aims to examine the feasibility and acceptability of a brief self-compassion intervention for adolescents with type 1 diabetes and disordered eating behaviour.

Methods and analysis: This feasibility study will examine the effectiveness of a brief self-compassion intervention, compared to a waitlist control group. Participants aged 12-16 years will be recruited from three diabetes outpatient clinics in Auckland, New Zealand. The brief self-compassion intervention is adapted from the standardised 'Making Friends with Yourself' (MFY) intervention and will be delivered in a group format over two sessions. As well as examining feasibility and acceptability through the flow of participants through the study and qualitative questions, we will assess changes to disordered eating behaviour (primary outcome), self-care behaviours, diabetes-related distress, self-compassion, stress and glycaemic control (secondary outcomes). Such data will be used to calculate the required sample size for a fully powered RCT.

Ethics and dissemination: The current trial has received ethics approval from the Health and Disability Ethics Committee (HDEC; research project number A+8467). Study results will be disseminated through peer-reviewed journals and conferences.

Trial registration number: ANZCTR (12619000541101).

Strengths and Limitations:

- The study will be the first to examine self-compassion as a potential therapeutic approach to the widespread problem of disordered eating behaviour in adolescents with type 1 diabetes.
- Qualitative data, changes to self-reported psychological health, and HbA1C will be used to examine the program's feasibility, acceptability and to estimate the magnitude of any effect of self-compassion on disordered eating behaviour.
- The study is limited by the lack of blinding by the first author.
- The study is a feasibility trial and therefore will not be able to determine the efficacy of the brief self-compassion program.
- Overall, the study will contribute to the future research agenda of developing a 'clinically usable' self-compassion intervention for adolescents with type 1 diabetes.

Introduction

This protocol paper describes a feasibility study designed to evaluate the feasibility, acceptability, and estimate of the effect of a brief self-compassion intervention for adolescents with type 1 diabetes (T1D) and disordered eating behaviours. Adolescents with T1D face the dual challenge of learning how to manage their chronic condition while concurrently dealing with what can be normatively difficult developmental changes. Maintaining optimal self-management of T1D requires adherence to a complicated routine of daily self-administration of insulin and monitoring diet, energy expenditure and blood glucose levels (1). Adolescents must learn how to make these complex routines flexible enough to implement into their daily life including school, hobbies and other activities (2). Unsurprisingly, diabetes self-management tends to deteriorate during adolescence, with adolescents showing sub-optimal glycaemic control and higher rates of complications compared to adults or younger children (3).

Adolescents with T1D also show much greater rates of psychological disorders, especially eating disorders, than their healthy peers (4, 5). In a recent national Australian study of adolescents with T1D, 50% of female and 18% of male adolescents scored over the cut-off for disordered eating behaviour (6). Eating disorders have also been shown to be twice as common in adolescent females with T1D compared to their healthy peers (7) and rates of disordered eating in adolescents with T1D are rising (8, 9). Given that behaviours such as insulin omission and purging are associated with increases in diabetes-related complications (6, 10), this is concerning. Poor psychological health, including disordered eating, has the potential to make daily self-management decisions even more challenging and has known associations with lower rates of glucose testing and insulin adherence (11), poorer glycaemic control (12) and more frequent hospitalisations and complications (13). Therefore,

prioritising psychological health and wellbeing is an essential component of successful diabetes care and may be even more relevant during adolescence.

Despite the high prevalence of mental health disorders among adolescents with T1D, treatment options are limited. Current interventions to target psychological issues include psychopharmacology (such as antidepressants) and psychosocial interventions. Research has shown that individual and group-based interventions focused on improving family relationships, stress management, and coping skills can improve adherence, glycaemic control and quality of life (14). However, such interventions are rarely incorporated into standard diabetes care due to funding constraints and a lack of therapist availability (15, 16), as well as the logistical issues associated with family therapies. Furthermore, only one study has examined the use of an intervention specifically targeting disordered eating behaviour in adolescents with T1D (17). There is thus a strong need to develop interventions to treat psychological distress, especially disordered eating behaviour, that are acceptable to adolescents with T1D and can be realistically incorporated into routine clinical care.

Self-compassion is an emerging approach which may offer an effective method to improve psychological health and self-management among adolescents with T1D. Self-compassion appears highly relevant to the self-criticisms that commonly arise following difficulty adhering to complex self-management regimens. At its core, self-compassion is characterised by: (1) being aware of one's moment to moment experiences with a sense of emotional balance and non-judgement (mindfulness), (2) acknowledging that suffering and imperfection are part of being human (common humanity), and (3) taking an active role in being caring and understanding toward oneself (self-kindness) (18). Lower self-compassion has been closely linked to greater depression and anxiety (19), including in adults with diabetes (20, 21), while higher self-compassion is associated with less rumination, self-criticism, perfectionism, and fear of failure (18, 22). Self-compassion has demonstrated

benefits for those with chronic illnesses (including inflammatory bowel disease and arthritis), such as improved self-management and coping (23). Most recently, a standardised 8-week self-compassion programme for adolescents, 'Making Friends with Yourself' (MFY), adapted from the Mindful Self-Compassion (MSC) Program for adults (24), showed significant improvements in self-compassion, life satisfaction and depression, compared to a waitlist control group, in healthy adolescents (23). Mindfulness, social connectedness, anxiety, stress, resilience, curiosity and gratitude have also been shown to increase throughout the MFY programme (25, 26).

To date, MFY has not been trialled in adolescents with diabetes or any other chronic illness. However, a recent RCT compared the 8-week MSC Programme for adults with diabetes to a waitlist control group (21). Researchers found increased self-compassion was associated with reductions in diabetes-related distress, depression, and improvements in glycaemic control, both at post-intervention and at the 3-month follow-up compared to the waitlist control group.

Considering the vital role psychological health plays in diabetes-related outcomes (27) and the conceptual fit between the purpose of self-compassion training and the issues confronting adolescents with T1D, we developed a brief (2-session) self-compassion intervention targeted to adolescents with T1D and disordered eating behaviour. The current study will examine the programme's feasibility and acceptability for adolescents with T1D and provide estimates of change in psychological and physical health outcomes. It is hypothesised that the brief self-compassion intervention will improve disordered eating behaviours, self-care behaviours, diabetes-related distress, self-compassion, stress and glycaemic control, compared to the waitlist control group at post-intervention.

Methods and analysis

Design overview

The study is a feasibility study of a brief self-compassion intervention (treatment group), compared to a waitlist control group, in 28 adolescents with T1D. The study will be conducted in accordance to the CONSORT guidelines (28) and has been prospectively registered in the Australian New Zealand Clinical Trials Registry (ANZCTR 12619000541101). The SPIRIT recommendations were adhered to in reporting the protocol (29).

Participants

Participants in the study are adolescents with T1D who are currently being recruited from three paediatric and adolescent diabetes clinics in Auckland, New Zealand. Adolescents are eligible for inclusion in the study if they meet the following criteria: (1) are aged 12 to 16 years, (2) diagnosed with T1D more than 6 months ago at time of recruitment and (3) demonstrate moderate to high instances of disordered eating behaviour on the Diabetes Eating Problem Survey Revised (DEPS-R) (30) screening tool. A moderate to high disordered eating behaviour cut-off score was chosen to allow more room to detect changes and to offer the interventions to those at the highest risk. Exclusion criteria includes: (1) non-English speaking adolescents, (2) adolescents with developmental disorders (e.g. Autism Spectrum Disorder), (3) adolescents diagnosed with a serious mental disorder requiring ongoing treatment (e.g., psychosis), (4) children with untreated hypothyroidism, and (5) children recently (in previous 48 hours) diagnosed with DKA or severe hypoglycaemia. See Figure 1 for an overview of the proposed flow of participants through the study.

Sample size calculation

Based on other studies suggesting the prevalence of disordered eating of 27% for boys and 42% for girls in T1D (31), we estimated that we would need to screen approximately 50 adolescents to enroll at least 20 adolescents (who score over the cut-off on the DEPS-R). We

will use the observed changes in psychological outcomes (e.g., DEPS-R) and physical health outcomes to calculate the required sample size for a subsequent fully powered RCT.

Intervention development

The brief self-compassion intervention was adapted from the 8-week MFY programme (25), in consultation with Karen Bluth and five other trained MFY and MSC teachers. Components from the MFY programme were chosen for the brief adaption because they are: (1) foundational exercises covering the basics of mindfulness and self-compassion and (2) address body image concerns and feelings of isolation, which have been highlighted in the literature to be relevant to adolescents with T1D (32). These components included group exercises and discussions, topics, art activities, meditations and individual reflection exercises (see Table 1).

Brief self-compassion intervention

The brief self-compassion intervention will involve two 2-hour sessions conducted at the University of Auckland. The intervention sessions will be facilitated by the first author (A.B), a trained MFY teacher.

As summarised in Table 1, Session 1 will focus on giving participants an understanding of mindfulness through several tangible activities including a mindful movement activity, group discussions and a mindful activity using a stone or shell. Psychoeducation around adolescent brain development and emotion regulation systems (33) will be taught to help to establish the reasons why mindfulness and self-compassion can help with managing stress, especially in adolescence. Regarding self-compassion, the 'How Would I Treat a Friend' exercise offers an interactive method of explaining self-compassion before practicing the self-compassion coping skills of 'Comforting Gesture' (i.e. 'Soothing Touch') and the 'Three Steps of Self-Compassion' (i.e. 'A Moment for Me').

Table 1: Key Exercises and Educational Components of the Brief Self-Compassion Intervention for Adolescents

Session one	Session two
Topic: what is self-compassion?	Meditation: Loving kindness meditation
Mindful movement activity: stop and be meditation	Topic: Summary of last week's content
Topic: mindfulness and the wandering mind	Topic: self-esteems vs. self-compassion
Mindful observation activity: here-and-now stone	Discussion: the cost of social comparison
Topic: the adolescent brain	Meditation: Compassionate body scan
Self-compassion exercise: how would I treat a friend?	Group exercise: crossing the line
Self-compassion exercise: comforting gesture	Compassionate letter
Self-compassion exercise: three steps of self-compassion	
Meditation: music meditation	

The 'How Would I Treat a Friend' exercise shows adolescents that they often treat themselves much more harshly than they treat their friends through exploring their reactions to how they would treat themselves versus their friends in difficult situations, such as receiving a bad mark on an important test. Finding a 'Comforting Gesture' (such as holding your hands over your heart or stomach), involves practicing applying self-compassion to soothe and regulate emotions during stressful situations in one's life. The 'Three Steps of Self-Compassion' involves applying the three elements of self-compassion (mindfulness, common humanity and self-kindness) to cope with difficult emotions.

Session 2 is focused on developing coping skills to deal with body image concerns and feelings of isolation. Opening with a loving-kindness meditation will provide a reminder

of the concept of self-compassion and the 'Comforting Gesture' tool from Session 1 before summarising the content taught in the last session. Self-esteem versus self-compassion and the cost of social comparison is then discussed to help teens understand how comparing themselves to others can create suffering and to allow them to practice using the coping skills taught in Session 1 when they experience feelings of inadequacy. The 'Crossing the Line' group activity then emphasises the common humanity element of self-compassion by asking adolescents to cross a line of string if they have experienced certain feelings or situations, such as feelings of isolation, been bullied or having compared themselves to their friends or an image in the media. Adolescents will then practice a compassionate body scan meditation and writing themselves a compassionate letter as further skills to use surrounding body image concerns.

Handbooks will be given to participants to review topics and outline the coping skills taught in the sessions, with examples of situations where it may be helpful to use them. Recordings of the meditations used in the sessions will also be emailed to the participant's parent/ caregiver and the participant.

Study procedure

The study started recruitment on the 24th of May 2019 and is estimated to finish in late October 2019. Figure 1 depicts the flow of participants through the trial. Eligible families will be invited by diabetes nurse educators at their Paediatric Diabetes Service clinic appointments to participate in a study investigating body image concerns in adolescents with T1D. Interested participants will be referred to the first author (A.B), who will verbally explain the study to interested families. Once consent/ assent is given, the adolescents will complete the DEPS-R screening tool. Participants who score over the cut-off score for moderate disordered eating behaviour, will then be randomised to either the treatment group or a waitlist control group (who will receive the intervention after the treatment group has

completed post-intervention measures) on a 1:1 basis. Randomisation will occur via sealed envelopes labelled with sequential study numbers, prepared by a biostatistician independent of the study. As the first author (A.B) is responsible for both recruitment and teaching the program, blinding is unable to occur.

After randomisation, participants will also complete standardised questionnaires measuring self-care behaviours, diabetes-related distress, self-compassion and stress in clinic or online. After completing the intervention, participants will be given the same questionnaires as well as open-ended questions to assess the acceptability and feasibility of the programme. Participants in the waitlist control will then start the intervention.

Outcome measures

The primary goal of this feasibility study is to determine the feasibility and acceptability of the brief self-compassion intervention in the service of designing a larger, multi-centred, powered study. This will be assessed by evaluating whether adolescents with T1D are willing to participate in the intervention (i.e. recruitment and uptake), reasons for not wanting to participate, the acceptability of the delivered intervention (assessed via qualitative questions), study attrition rate and the suitability of the outcome measures. Qualitative data, through questionnaires at post-intervention, will also be used to refine the intervention content and comment on strengths and weaknesses of the program.

In addition, the following psychological and physical health outcomes will be assessed to give preliminary estimates of effect sizes to estimate the sample size needed for a fully-powered RCT:

1. Disordered eating behaviour as measured by the Diabetes Eating Problem Survey Revised (DEPS-R) (30). The DEPS-R is a 16-item diabetes-specific self-report measure of disordered eating. Participants are asked how true each item is for them (e.g., 'I feel fat when I take all of my insulin') on a 6-point Likert scale

(0=never to 6=always), with items summed to produce a total score. The scale has demonstrated good reliability (α=0.86-0.91) and validity in adolescents with diabetes samples (30, 34, 35). For the current study, the moderate disordered eating cut-off (≥10) for inclusion in the study will be used. DEPS-R results for all adolescents screened for eligibility will be reported to give an indication of prevalence of moderate disordered eating behaviour in the Pediatric Diabetes clinics.

2. Self-care behaviours as measured by the Self Care Inventory-Revised Version (SCI-R) (36). The SCI-R is a 15-item questionnaire which assesses how often diabetes self-care behaviours have been adhered to over the past one to two months on a 5-point Likert scale (1=never to 5=always). The self-care behaviours assessed include the main components of the type 1 diabetes self-management routine such as monitoring and recording glucose levels, administering and adjusting insulin and regulating meals and exercise. Items will be averaged and converted to a 0-100-point scale to produce a total score, with higher values representing better self-care. The scale has shown good reliability (α=0.77-0.78) and validity (37, 38).
3. Diabetes-related distress as measured by Problem Areas in Diabetes Survey (PAID) (39). The 20-item questionnaire lists common negative emotions related to living with diabetes such as, 'feeling alone with diabetes', and 'worrying about the future and the possibility of serious complications'. The 20-items are measured on a 6-point Likert scale (1=not a problem to 6=a serious problem), with items averaged to produce a total score. The scale demonstrates good reliability (α=0.93) and validity (40).

4. Self-compassion as measured by the Self-Compassion Scale, short form (SCS-SF) (41). The 12 items are measured on a 5-point Likert scale (1=almost never to 5=almost always), with items averaged to create a total score. Example items include: 'when I fail at something important to me I become consumed by feelings of inadequacy' and 'when I'm feeling down I tend to obsess and fixate on everything that's wrong'. Reliability for this scale is good with a Cronbach alpha of $\alpha = 0.77$-$.79$ (25, 26) in adolescent samples. Strong predictive, convergent and discriminant validity has also been demonstrated (42, 43).
5. Stress as measured by the Perceived Stress Scale (PSS) (44). The questionnaire assesses feelings of stress, hassles and coping during the past month. For example, 'in the last month, how often have you felt that you were unable to control the important things in your life?'. The 14-items are measured on a 5-point Likert scale (0=never to 4=very often), with the score of each item combined to produce a total score. The scale has been shown to associate with glycaemic control (45) and demonstrates good reliability (α=0.75-.88) and validity (46).
6. Glycaemic control as measured by Glycosylated haemoglobin (HbA_{1C}). HbA_{1C} is a blood test collected during routine outpatient appointments (which occur every 3-4 months), which is a reliable measure of blood glucose control over a period of 3-4 months. HbA_{1C} is measured in millimoles per mol (mmol/mol), with lower values indicating better glycaemic control (47). HbA_{1C} ranges from 31 to 108 mmol/mol, with the ideal target for all child and adolescent age groups being below 58 mmol/mol (1). HbA_{1C} levels will be accessed from clinical records at baseline and post-intervention (window of 12-16 weeks after baseline).

Data analysis plan

Descriptive statistics will be reported for proportion of adolescents who were screened and who scored over the cut-off for the DEPS-R, rates of disordered eating across all adolescents screened, number of adolescents who attended the sessions, and number of adolescents who dropped out of the study. Data will be tested for violations of statistical assumptions. If parametric assumptions are not met, the Mann-Whitney test will compare the two groups at time 2 and Wilcoxon signed-ranks test will analyse possible within-group improvements. Means, standard deviations and 95% confidence intervals will be reported with the analyses. Pearsons correlations will be used to explore the relationships between the different outcome measures, demographic characteristics, disease characteristics, and current insulin regimen. An independent samples t-test will be conducted at post-intervention (see time 2, Figure 1) and will be our main analysis to test our hypothesis for differences between the intervention group and waitlist control group in disordered eating behaviour, diabetes-related distress, stress, self-care behaviours and self-compassion. An independent samples t-test will also be conducted at the 12-week follow-up to assess any possible differences between groups for glycaemic control. In addition, to increase sample size and statistical power, an exploratory analysis will combine post-intervention data from participants in the treatment group (at time 2) and participants in the waitlist control group (at time 3) to examine within and between group changes from baseline, using paired samples t-tests. An intention to treat analysis is planned.

These effect size estimates will also allow us to estimate the required sample size for a future RCT. Mean differences, standard deviations and sample size will be used to calculate an estimated Cohen's d for the effect of the intervention on disordered eating behaviour, which we will then use to calculate our required sample size.

Patient and Public Involvement

Patients, carers and members of the public were not involved in the study design phases of the current study. However, during the recruitment process patients who choose not to participate will be asked to assess whether the time commitment or required travel was a reason for not choosing to participate, when possible. In addition, patients who participate in the sessions will also provide qualitative feedback on the burden of participating, the recruitment process and the format and content of the sessions to inform the future RCT. Regarding dissemination of results, during recruitment we ask patients whether they consent to the findings being disseminated via peer reviewed journal articles and conferences. We also ask whether they would like to be informed of the results at the end of the study and how (e.g. email/post). Patients who agree to being informed of the study results are sent a letter with the key findings and any publications arising from the study. In some cases, patients may also be invited to a departmental presentation of the study findings.

Ethics and dissemination

The study was approved by the Health and Disability Ethics Committee (HDEC; research project number A+8467). Due to screening for and only including adolescents with disordered eating behaviour, it was recommended to include a waitlist control group (rather than a standard care control group) in order to offer all eligible participants the intervention. Participants who report significant psychological concerns, such as self-harm, or issues relating to their diabetes that fall outside of the scope of the intervention, such as complex self-management concerns, will be referred to the diabetes team psychologist. The paediatric and adolescent diabetes team (including endocrinologists, diabetes nurse educators, dieticians and a psychologist) will provide study support throughout the trial, including monitoring any adverse events. Study results will be disseminated through peer-reviewed journals, a doctoral thesis, and conference presentations.

Discussion

To our knowledge, the current study will be the first to assess the acceptability of self-compassion intervention for adolescents with T1D and examine the feasibility of a brief adaption of the MFY programme. The intervention addresses the rising concern of disordered eating in adolescents with T1D (8, 9), building on the sparse literature in this area (17). The intervention will aim to teach adolescents evidence-based mindfulness and self-compassion skills to help them cope with stress, difficult emotions, self-management obstacles, and body image concerns and to determine whether self-compassion is a feasible and acceptable approach. As the prevalence and impact of these psychological concerns in adolescents with T1D is a current obstacle in diabetes care, the study will help determine whether self-compassion is a feasible and acceptable approach.

The novelty of testing self-compassion for adolescents with T1D and the brief format of the intervention are key strengths of this study. Firstly, although self-compassion has previously demonstrated efficacy in adults with diabetes (21) we believe it may be even more beneficial for adolescents with T1D. Adolescence is a period of vulnerability with an increased risk for self-criticism, poor self-esteem, and body image concerns (48). In adolescents with T1D these concerns are exacerbated by difficult self-management routines and parental conflict surrounding their diabetes-care (49), as well as increased risk of psychological distress and feelings of isolation (32). Self-compassion may encourage adolescents to be more accepting and kind to themselves when facing these issues, without engaging in problematic or counterproductive self-criticism. The common humanity aspect of self-compassion is likely to help validate feelings that emerge from any struggles they are experiencing, such as feelings of isolation, feeling less than, stress and sadness, as normal and common to all teens.

An adapted version of the ‘Making Friends with Yourself’ programme to a brief (2-session format) was chosen to address the lack of ‘clinically usable’ interventions in diabetes

care. Although it is widely acknowledged that psychological care is a key component of improving health outcomes in diabetes (16, 27), the integration of psychosocial care into routine diabetes care remains lacking. Despite the growing literature demonstrating the efficacy of psychosocial interventions for improving psychological outcomes in T1D, interventions are rarely designed with the intention of being 'clinically usable' and in a format that could potentially be adopted into standard care.

Altogether, our aim is to examine the feasibility and acceptability of a brief self-compassion intervention, as well as provide effect size estimates. If the brief self-compassion intervention is found to be feasible and acceptable to adolescents, future plans include conducting a fully powered RCT to examine the long-term efficacy of the intervention, with the intention of developing a clinically usable psychosocial intervention for youth with both T1D and disordered eating behaviours.

Authors contributions: A.B, P.H and A.S came up with the conception and design of the study. A.B will be recruiting participants and conducting the program sessions. P.H and C.J will provide guidance and assistance with recruitment. K.B provided training and consultation during the program development phase and will provide A.B with supervision throughout the sessions. A.B. and A.S. wrote the manuscript. N.C., P.H, C.J and K.B reviewed and edited the manuscript.

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Competing interests statement: The authors declare that they have no conflicts of interest.

Figure 1 Legend: CONSORT flow diagram showing the proposed flow of participants (n=28) through each stage of the feasibility trial (enrolment, disordered eating screening, baseline assessment, randomisation to either intervention group or waitlist control, time 2 assessment, time 3 assessment and collection of HbA1c).

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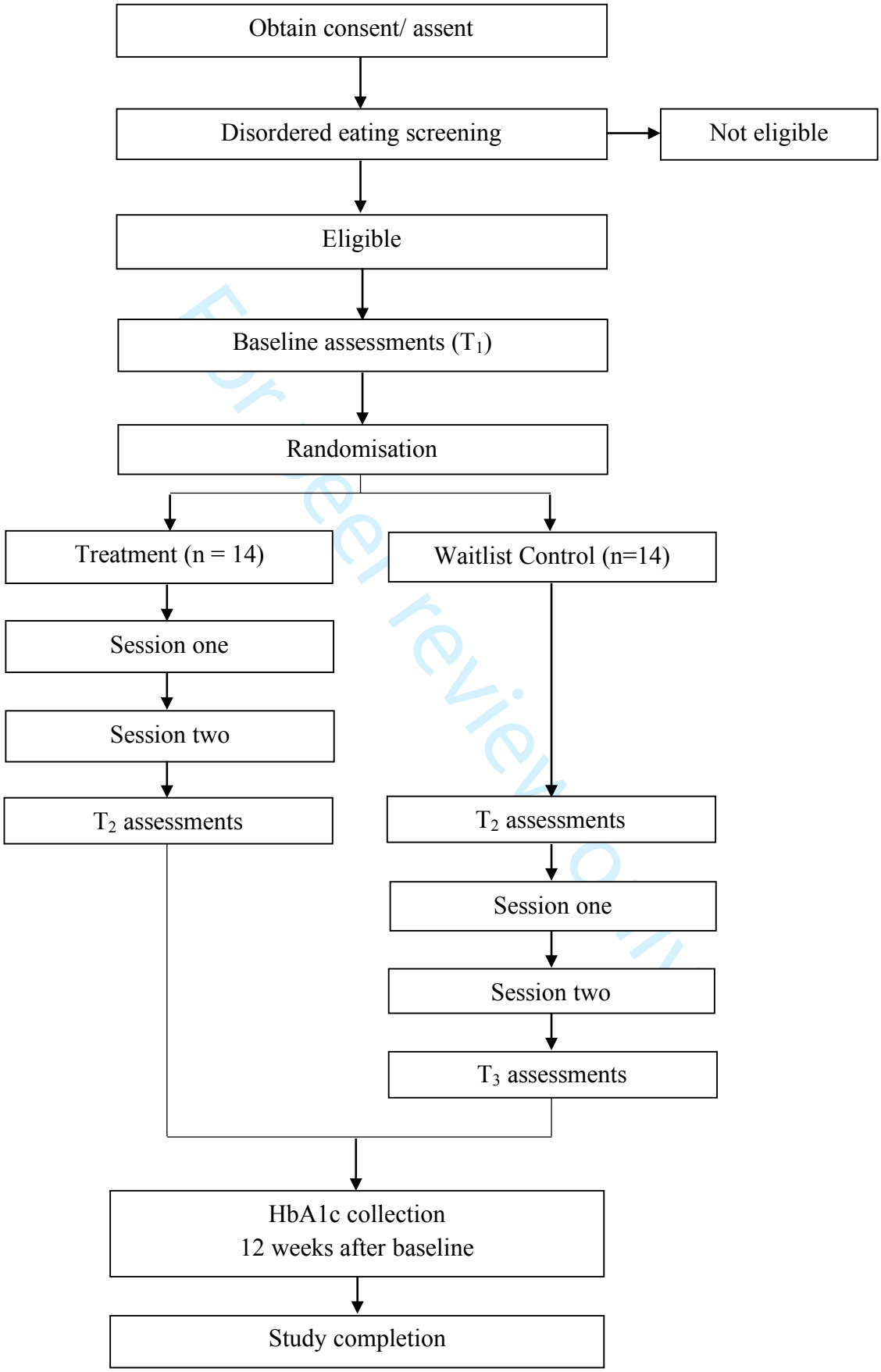
Figure 1: Flow of participants through the study



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

Section/item	Item No	Description	Page Number, on which item is reported
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	p.1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	p.2
	2b	All items from the World Health Organization Trial Registration Data Set	na
Protocol version	3	Date and version identifier	p.1
Funding	4	Sources and types of financial, material, and other support	p.17
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	p.1 & 17
	5b	Name and contact information for the trial sponsor	na
	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	na
	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)	na
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	p.4-6
	6b	Explanation for choice of comparators	p.14
Objectives	7	Specific objectives or hypotheses	p.6
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)	p.7
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	p.7
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)	p.7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	p.8-9
	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)	p.14
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	na
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	na
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	p.10-13

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)	p.21
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	p.7
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	na
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	p.10
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	p.10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	p.10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	p. 10
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	na
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	p.10-13

	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	na
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	na
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	p. 13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	p.13
	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)	p.13
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	na
	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	na
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	p. 14
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	na
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	p.14
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)	p.7
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	p.10
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	na
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	na
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	p.16
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	na
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	p.14
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	p.14
	31b	Authorship eligibility guidelines and any intended use of professional writers	p.17
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	na
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	na

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	na