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Title

Accounting for health literacy and intervention preferences when reducing unhealthy snacking: Protocol for an online randomized controlled trial

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Abstract

Introduction

Health literacy interventions are typically implemented using the 'universal precautions approach' in which all consumers are presented with simplified materials. Whilst this approach has shown to improve knowledge and comprehension, its impact on complex behaviours is less clear. Systematic reviews also suggest that health literacy interventions underutilise volitional strategies (such as planning and self-monitoring) that play an important role in behaviour change. Furthermore, a recent study found that volitional strategies may need to be tailored to the participant's health literacy level. The current study aims to replicate these findings in a sample of people who have diabetes and/or are overweight or obese as measured by BMI, and to investigate the most effective method of allocating an action plan to a participant to reduce unhealthy snacking.

Methods and analysis

We plan to recruit approximately 2,400 participants at baseline. Participants will receive one of two alternative online action plans intended to reduce unhealthy snacking ('standard' action plan or 'literacy-sensitive' action plan). Participants will be randomised to a method of allocation to an action plan: 1) random allocation; 2) allocation by health literacy screening tool; or 3) allocation by participant selection. Multiple linear regression will be used to evaluate the impact of health literacy on intervention effectiveness. The analysis will also identify the independent contributions of each of the action plans, method of allocation, health literacy, and participant selections on unhealthy snacking at 4-week follow-up.

Ethics and dissemination

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This study was approved by the University of Sydney Human Research Ethics Committee [2017/793] and is registered with Australian New Zealand Clinical Trials Registry: ACTRN12618001409268p. Findings will be disseminated through peer-reviewed publications in international journals, conferences and updates with collaborating public health bodies (Diabetes NSW & ACT, and Western Sydney Local Health District).

Article Summary

Strengths and limitations of this study

- The impact of literacy-sensitive design on the effectiveness of an action plan intervention to reduce unhealthy snacking in a sample of people with diverse health literacy levels will be evaluated.
- The analysis will isolate the effects of each action plan intervention (standard and literacy-sensitive) from the effects of allocation method (random, screened or choice), the participant's health literacy (as categorised using the screening tool) and the effect of providing a choice of interventions.
- Free-text plans in this study will undergo content analysis to assess the quality of plans created by people with higher and lower health literacy.
- The impact of assessing participant preference prior to random allocation to an intervention on outcomes will also be explored.
- A subjective outcome measure (self-reported monthly unhealthy snacking collected at a single time-point) rather than an objective measure (e.g. unhealthy snacking observed throughout the month-long period) will be used, which may limit the study findings.

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Introduction

Low health literacy is increasingly recognised as an important contributor to health inequality and is associated with increased hospitalization, mortality, prevalence of chronic disease and risk factors for health conditions (1). Current approaches to address health literacy issues have focused on providing all consumers, regardless of their health literacy level, with health information that is easy to process and understand (1, 2). Whilst this 'universal precautions approach' has been shown to improve health knowledge, it is less clear whether it is effective for improving complex behaviours such as healthy eating and increased physical activity (1, 3, 4). This may reflect the fact that health literacy guidelines and interventions place relatively little emphasis on strategies that promote action, such as planning, self-monitoring or problem solving (5-9). These kinds of strategies are increasingly recognised as key components of lifestyle interventions (10); furthermore, there has been little research investigating how they could be adapted for audiences with lower health literacy.

A recent randomized control trial (RCT) has investigated the effects of literacy-sensitive design on action plans to reduce unhealthy snacking behaviour (11). This design incorporated health literacy strategies (e.g. simple language) and separated the planning process into distinct steps to reduce cognitive demands. This 'literacy-sensitive' action plan was compared to action plan instructions that have been used in samples of the general population (12). The results from this study suggested that people with lower health literacy reported consuming fewer unhealthy snacks at follow-up when they had used the literacy-sensitive action plan, whereas people with higher health literacy reported consuming fewer unhealthy snacks using the 'standard' action plan (11).

The current study will build on these findings by evaluating the most effective way to determine the best action plan for participants. One obvious approach is to allocate an action

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plan based on a participant's health literacy score. Alternatively, participants could be asked to select the plan they would prefer to follow. Although allowing the participant to choose their plan might less accurately match a participant to an action plan that meets their health literacy needs, there are some potential additional advantages to this approach. For example, participants would be able to factor in other relevant aspects (such as engagement) (13), and presenting participants with different options may also encourage greater satisfaction with the intervention (14). This is further supported by evidence that the effects of interventions in randomized controlled trials may be increased when participants receive their preferred intervention (15).

This study has three key aims. Firstly, this study aims to evaluate the impact of health literacy and a literacy-sensitive action plan on unhealthy snacking in a sample of people with type 2 diabetes and/or overweight or obese BMI. In doing so this study aims to replicate previous findings in a clinical sample (11).

The second aim is to evaluate how the *method of allocation* to an action plan affects the overall effectiveness of the intervention. Three methods of allocation will be evaluated: 1) random allocation; 2) allocation based on individual health literacy; or 3) allowing participants to choose. Furthermore, this study will employ a two-stage randomization (Rucker) design (16) to identify the independent contributions of each of the action plans, the method of allocation (effects of the screened and choice arms), healthy literacy, and action plan selection.

The third aim is to evaluate whether assessment of participant preference for an intervention prior to random allocation influences the effectiveness of the intervention.

We hypothesise that:

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1. A literacy-sensitive action plan will be more effective at reducing unhealthy snacking for participants with lower health literacy, whereas the standard action plan will be more effective for participants with higher health literacy.

2. The intervention will be more effective at reducing unhealthy snacking for participants who are allocated an action plan using the health literacy screening tool compared to those who are asked to select their preferred action plan. Both of these allocation methods will be more effective than random allocation to an action plan.

3. Assessing preference will negatively impact plan effectiveness, an effect which will be greater for those who are randomised to the plan which is discordant with their preference.

Methods and analysis

Study Design

The design is a three parallel-arm online RCT to test the effect of health literacy, type of action plan, and method of allocation to an action plan on self-reported unhealthy snacking behaviour. The three methods of allocation are 1) random 2) use of a health literacy screening tool to allocate participants one of the two action plans ('screened' arm) and 3) participant choice of action plan ('choice' arm). This study will also evaluate whether the process of assessing preference for a particular action plan prior to randomisation will have an impact on subsequent self-reported snacking behaviour. A schematic representation of the study design is shown in Figure 1.

Participants and recruitment

The proposed study will seek to recruit 2,352 Australian participants with type 2 diabetes. Participants will be recruited through an online market research company, Research Now

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Survey Sampling International (RN SSI), which has a pool of approximately 10,000 Australians with type 2 diabetes. This sample will be supplemented with additional participants from RN SSI who have self-reported height and weight corresponding to an overweight or obese BMI (i.e., BMI $\geq$ 25 kg/m^2). Participants will be eligible to participate if they are registered with RN SSI's Australian registry, are over 18 years of age (adult population), and self-report that they have type 2 diabetes or self-report a height and weight that correspond to overweight or obese BMI. Participants will be excluded if they do not speak English. Participants will not be excluded on the basis of their snacking behaviour.

Participants who click the link received from RN SSI will be presented with a brief introduction to the study and a link to the Participant Information Sheet. Informed consent will be indicated by completion of the online survey, as outlined in the Participant Information Sheet. On the next page, participants then begin the baseline survey.

Patient and public involvement

Patients and public were not directly involved in development of the research question, however, consumer health representatives living with type 2 diabetes were consulted for feedback at multiple stages of intervention and study development, including: intervention instructions, the appropriateness of the literacy sensitive plans, and the ease with which feedback at follow-up could be communicated. Participants in the trial are able to indicate if they are interested in receiving a lay summary of the study results which will be disseminated through email by RN SSI (further maintaining participants anonymity). We will also assess participant burden and acceptability using the pilot data. Lastly, participants will be able to provide feedback on the perceived burden of the intervention using free text fields during the follow-up survey.

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Participant allocation

After completing baseline measures participants will be automatically randomised to one of three allocation methods using the 'Survey Flow' and 'Randomiser' functions included in the survey platform (Qualtrics) (Figure 1). The 'Randomiser' is based on the Mersenne Twister, a pseudorandom number generator. This allocation method will determine how the planning tool (either literacy-sensitive or standard) is assigned to the participant. Participants in the random arm will be unaware of their allocation method. At baseline, only the participants in the choice arm and those who are randomised to assess prior preference in the random arm will be aware of the two different tool versions. Participants in the screened arm will be aware that there is more than one tool available.

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[Figure 1 here]

Figure 1: Anticipated participant recruitment and attrition to achieve sufficient sample size

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Allocation method

1. **Random (Arm A):** Participants randomised to the 'random' arm will be further randomised to either 1) assess their prior preferences (i.e. their preferred action plan; Arm A1), and then randomised to the standard or literacy-sensitive action plan; or 2) randomised to the standard or literacy-sensitive action plan without assessment of prior preferences (Arm A2; Figure 1). Prior preference will be measured using the same format as in the 'participant choice' arm (Arm C) with additional text stating that participants may not receive their preferred tool.
2. **Screened (Arm B)**: Allocation is based on assessment of health literacy using the Newest Vital Sign (NVS) measure. The literacy-sensitive action plan will be allocated to those scoring less than 4 (indicative of inadequate health literacy), and the standard action plan will be allocated to the remaining participants. Participants will be told that, based on their responses, the researchers have selected an action plan tool that is most suitable for them.
3. **Choice (Arm C)**: Participants will be provided with a brief description of the action plans and select the plan they want to use. Order of presentation of the two plans is randomised. In the first instance, participants have the option of selecting 'Unsure' to allow for undecided participants. Participants will then be presented with an alternative description of the study and asked again to make a choice. Participants will be informed that if they select 'Unsure' again, the researchers will select a plan for them. In doing so, participants will be randomised to an action plan as per Rucker protocol (16).

Action plan interventions

Either a literacy-sensitive or standard action plan will be allocated to participants. The text used in each tool is presented below:

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Literacy-sensitive action plan ("Smart Snacking 101 (basic)"): This consists of 4 steps that guide the participant through the process of developing an appropriate plan (also shown in Figure 2):

1. Step 1: Sometimes we snack because we are hungry, but there are lots of other reasons. Think about your snacks in the last week. Below is a list of 'snack moments.' These are times when people tend to choose unhealthy snacks or eat too much. Choose 3 snack moments from the list that happened to you the most often in the last week. [Participants selects from list of snack moments].
2. Step 2: Below are your top 3 snack moments. Some snack moments will be more important than others. Choose the 1 that you would be happiest to change. [Participant chooses from 3 previously selected snack moments]
3. Step 3: Great! Your most important snack moment was snacking because you are [example snack moment: bored]. The last step is to come up with a plan! Choose the solution that you think will work best for you. Drag it into the space on the right. [Participants selects from list of solutions]
4. Step 4: Imagine how your plan might feel. [examples of scenarios when this might happen]. The final step is to make sure the plan is realistic. How hard do you think it will be to do this plan for the next month [Slider options range from very easy (1) to very hard (10). If the participant selects a number greater than or equal to 7 they will be prompted to revise the plan]

[Figure 2 here]

Figure 2: Mobile screenshots from *literacy-sensitive action plan*. From left to right: a) Step 1: Selecting top 3 snacking scenarios; b) Step 2: Selecting 1 key scenario; c) Step 3: Selecting a solution; d) Step 4: Imagining the plan

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Standard action plan ("Smart Snacking Pro (advanced)"): Participants receive the following instructions: "We want you to plan how you will change your unhealthy snacking behaviour each day, because forming plans has been shown to improve snacking habits. You are free to choose how you do this but we want you to formulate your plans in as much detail as possible. Pay attention to the situations in which you will implement (carry out) these plans. Focus on situations when you are not hungry but find yourself snacking. Please enter your situations and your plans below."

After completing either action plan participants will be presented with their plan for a final time and instructed to write down, take a screenshot or make a copy of it. Participants will also be asked to confirm that they have a copy of the plan.

Baseline and follow-up surveys

At baseline participants will complete demographic questions and measures of health literacy. They will then receive information about general reasons for reducing unhealthy snacking and a definition of unhealthy snacks. Participants then complete measures of snacking behaviour, habit strength (concerning consumption of unhealthy snacks), and intentions to reduce unhealthy snacking. Intention to reduce unhealthy snacking will be measured again, immediately after creating the plan. Participants will be emailed a reminder of their personal plan at baseline (within the first week), and before then end of the 2nd and 3rd weeks to increase compliance and retention. Participants will complete a follow-up survey after 4 weeks. The follow-up survey consists of the same description of reasons to reduce unhealthy snacking and definition, followed by measures of snacking behaviour, habit strength and intention. Action control will also be measured in the follow-up survey.

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Measures

Screening measures

Prior to beginning the survey, participants will be asked to indicate whether they have type 2 diabetes, and to provide their height (cm or feet and inches) and weight (kg).

Demographic measures

Participants will be asked to complete questions about their age, employment status, highest level of educational attainment, and, if they report having diabetes, years since diagnosis and whether or not they use insulin.

Health literacy

Health literacy will be measured using the Newest Vital Sign (NVS)(17), a 6-item measure of functional health literacy, and a single-item literacy screener (18). NVS scores of 0-1 indicate a high likelihood of limited healthy literacy, scores of 2-3 indicate the possibility of limited health literacy and scores of 4-6 indicate adequate health literacy.

Need for cognition

Three items on a 7-point likert scale (strongly disagree to strongly agree) will assess the participant's need for cognition (19).

Snack scores (previous month)

Snacking scores will be measured using a validated 7-item measure based on a diet score developed by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) (20). Items are drawn from the 'discretionary foods' category which the Australian Guidelines to Healthy Eating define as foods 'not considered necessary for a healthy diet'. Alcohol and sugar sweetened beverages are excluded from the assessment in this study as the focus is on 'snacks.' Participants answer how many serves of unhealthy snacks they ate in the past month. Participants can answer according to the number of serves per day, week or month. Average weekly serves of unhealthy snacks will be calculated from these scores.

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Perceived unhealthy/healthy snacking (previous week)

Two items, each on a 7-point Likert scale will assess perceived extent of healthy and unhealthy snacking in the previous week, respectively.

Snacks consumed (previous day)

Participants will be asked to select from among 26 items the snacks that they had consumed in the previous day. This list includes unhealthy and healthy snacks and is based on previous work (21).

Intention, habit strength and action control

The measure of intention consists of 3 items that ask about the participant's intention to reduce unhealthy snacking (22, 23). Habit strength will be assessed using the 12-item self-report habit strength index (24), and action control will be assessed using a 6-item measure (25). Responses to each item are recorded on 7-point Likert scales (strongly disagree to strongly agree).

Difficulty using the planning tool

A single item will ask participants to rate how hard it was to use the planning tool (1=not at all hard, 5=extremely hard).

Preferred action plan at follow-up

At follow-up, participants will be reminded of the name and logo used for their plan. Participants will be shown an image slider that contains screenshots from the other action plan. Participants will then be asked: "If you were given the choice, which action plan would you prefer to use next time?"

Sample size

The proposed study will seek to analyse a sample of 2,000 Australian participants at follow-up with high BMI (overweight/obese) and/or type 2 diabetes. At baseline participants will be

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randomised at a ratio of 2:1:1 to each allocation method arm, such that there are a total of 1,000 participants in the random arm (who will then be evenly randomised to assess or not assess their preference for a particular action plan before they are ultimately randomised to an action plan), and 500 in the two remaining allocation method arms (the screened and choice arms). With a two sided alpha of 0.05 and power of 80%, a sample of this size will allow us to detect a small main effect of $f = 0.08$ in a univariate ANOVA comparing the three allocation method arms and in a univariate ANOVA comparing the two prior-preference assessment arms; this corresponds to a minimum pairwise difference between the two most extreme mean values of approximately 0.18 standard deviations.

Based on our previous studies recruiting through this provider, we anticipate an attrition rate no greater than 15% by one month follow-up. Therefore, we estimate a total of 2, 352 should be recruited at baseline to ensure sufficient sample size for analysis.

A sample of this size will also ensure that there is at least 80% power for secondary analysis conducted to estimate treatment and preference effects (16, 26) with a treatment effect between the two interventions (literacy-sensitive and standard planning tools) as small as 0.25 standard deviations (estimated as 5 snacks per month based on previous findings (11)), and a preference effect, comparing those who received their preferred tool to those who did not, as small as 0.35 standard deviations (approximately 7 snacks per month). This assumes that approximately equal proportions of participants will choose the literacy-sensitive and standard planning tools in the choice arm, and that there will be approximately equal proportions of participants allocated to each of these interventions in the screened arm.

Piloting

The intervention will be piloted with 200 participants to check that approximately equal numbers of participants allocated to the choice condition select each of the interventions. If

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required, sample size estimates will be adjusted to ensure that the study is sufficiently powered. Piloting will also allow us to assess participant burden and intervention acceptability.

Analysis:

Only participants who have completed follow-up will be included for analyses of outcome variables. Baseline characteristics of completers and non-completers will be compared to assess bias and generalisability.

Confirmatory analysis

A confirmatory analysis will replicate the analysis previously reported (11) to examine if the treatment effect is modified by health literacy. Multiple linear regression models including an intervention group × health literacy (NVS score) interaction term will be used to predict follow-up snacking scores and perceived difficulty using the plan. Important correlates of health literacy (age, level of education, language spoken at home)(1), diabetes status and baseline snacking will be controlled for in the model. NVS scores will be examined both continuously and categorically (i.e., inadequate vs. adequate health literacy).

Assessment of prior preference analysis

For participants in the random arm of the study, participants whose action plan preference was assessed prior to randomisation to an intervention will be compared to those whose preference was not assessed. Multiple linear regression (controlling for health literacy, age, level of education, language spoken at home and baseline snacking) will evaluate the effect of preference assessment on unhealthy snacking behaviour. For participants who provided a preference, an additional multiple linear regression will evaluate the effect of participants receiving their preferred intervention compared to those not receiving their preferred intervention on unhealthy snacking behaviour.

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Analysis of effects of allocation method

The primary analysis will use regression to test for a difference in self-reported unhealthy snacking between the three randomised arms (random, screened, and choice) whilst adjusting for any effect of diabetes status. An adjusted model will also be constructed to allow for any baseline imbalances in the potential confounders including age, English as a second language, level of education. The analysis will be repeated on the secondary outcomes of perceived unhealthy snacking in the previous week, snacks consumed the previous day, difficulty using the planning tool, action control, and habit strength with similar adjustment for diabetes status and any baseline imbalances. A sub-analysis will also be conducted on participants with and without type 2 diabetes.

Treatment, preference and selection effects will be estimated for the primary outcome (16). The treatment effect compares the efficacy of the health literate action plan with the standard action plan in the random arm. The preference effect and selection effects are estimated using the random and choice arms. The preference effect measures the difference in self-reported unhealthy snacking for those who received their preferred action plan compared to those who did not receive their preferred action plan. The selection effect measures the difference between those who would select the literacy-sensitive intervention with those who would select the standard intervention regardless of which intervention they received. Secondary analyses will adjust for diabetes status, and baseline imbalances in potential confounders including age, English as a second language, level of education. Data from participants in the screened arm will also be analysed in this manner, producing estimates analogous to the preference and selection effects.

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These effects will also be estimated for the secondary outcomes of perceived unhealthy snacking in the previous week, snacks consumed the previous day, difficulty using the planning tool, action control, and habit strength with similar adjustment for diabetes status and any baseline imbalances.

Bootstrapping, by taking repeated random samples with replacement, will be used to estimate the difference between the preference effect (estimated using choice arm) and an analogous effect estimated using the screened arm, as well as the difference between the selection effect (estimated using the choice arm) and an analogous effect estimated using the screened arm. Bootstrapping will also be used to estimate the confidence intervals for non-continuous outcome measures. The bootstrapping is necessary, as the variances for the estimated differences and non-continuous outcomes have not been derived previously (27).

Additional analysis

Two researchers will also independently code standard action plans to indicate the extent that participants followed standard action plan instructions (that is, provided at least one 'situation', and one 'plan') and the extent that plans differed from the pre-determined options presented in the literacy-sensitive action plans (for example, situations or solutions that did not correspond to options listed in the literacy-sensitive action plan, or strategies that fell outside of the "If-then" construction. The latter may include, for example, making sure healthy snacks are prepared in advance, or refraining from buying certain foods at the supermarket). Coders will be blind to the health literacy level of participants. Any disagreements will be systematically resolved through discussion.

Data management

De-identified data will be captured electronically on the secure Qualtrics server. Data will be stored securely in de-identified form, with a unique participant ID to link responses from the

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baseline and follow-up surveys. In all forms of dissemination, only de-identified data will be presented as group means and differences to maintain the anonymity of participants. In line with National Health and Medical Research Council (NHMRC) recommendations, and University of Sydney policies, all data will be kept for a minimum 5 years

Ethics and dissemination

This study was approved by the University of Sydney Human Research Ethics Committee [2017/793]. The interventions used in this study are practical; they can be easily incorporated into existing self-management practices, particularly with the use of online technologies, and are low in cost. Ascertaining an effective way to tailor planning tools to health literacy level (that is, allowing the participant to choose by employing a screening tool) will provide valuable information for implementation in apps that target people with varying health literacy levels. Findings from this study will be disseminated through peer-reviewed publication and national and international conference presentations. Findings will also be disseminated through community and research partnerships with groups such as Western Sydney Diabetes.

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Authors' contributions

Conceptualisation, methodology, writing – review and editing: JA, CB, EC, RT, SW, KM

Investigation, project administration: JA

Writing – original draft preparation: JA, EC, RT

Software: RT

Supervision: EC, CB, KM

Funding acquisition: CB, JA, RT, KM

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Competing interests statement

Authors have no competing interests.

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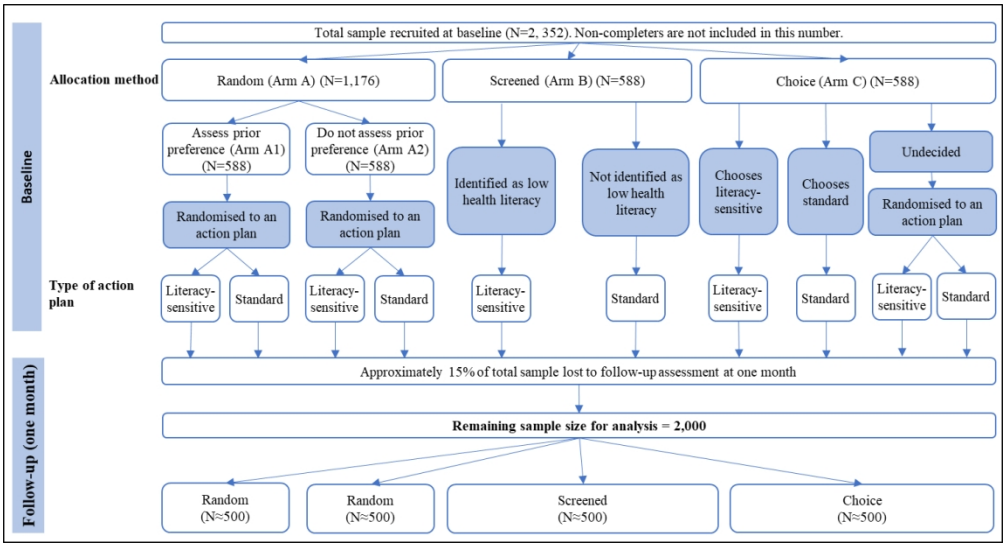

Figure 1: Anticipated participant recruitment and attrition to achieve sufficient sample size

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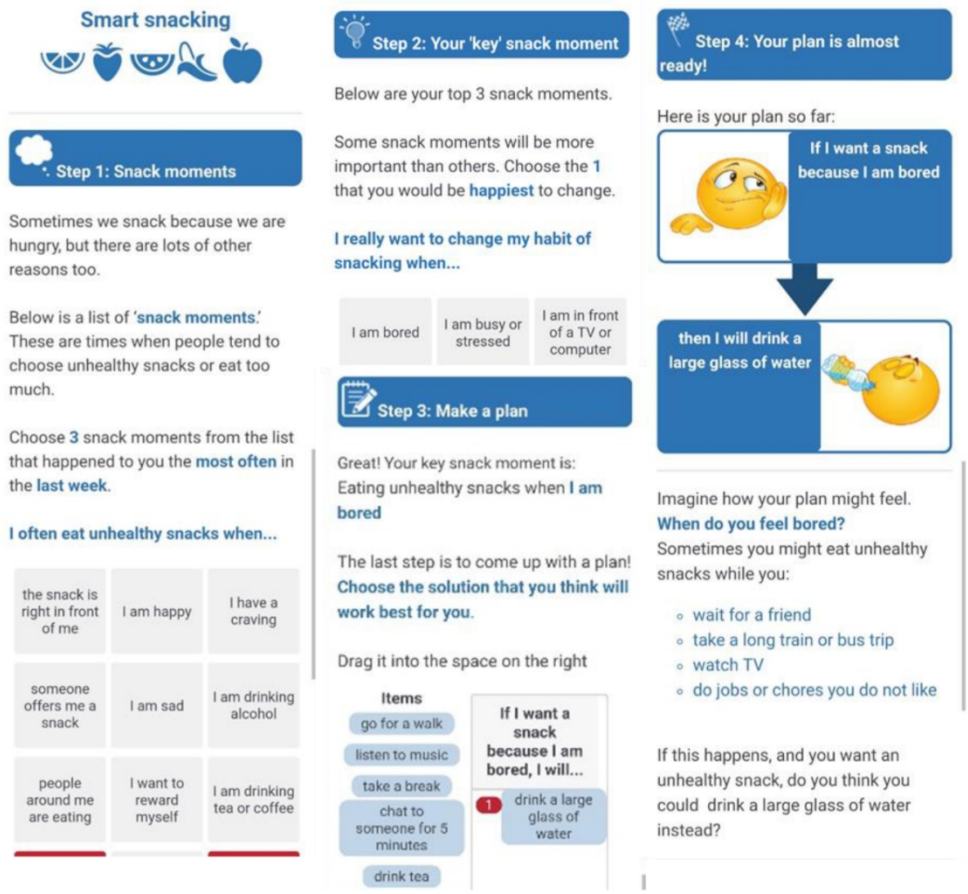

Figure 2: Mobile screenshots from literacy-sensitive action plan. From left to right: a) Step 1: Selecting top 3 snacking scenarios; b) Step 2: Selecting 1 key scenario; c) Step 3: Selecting a solution; d) Step 4: Imagining the plan

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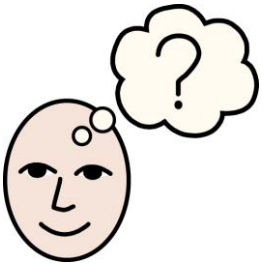
THE UNIVERSITY OF SYDNEY

Study Information Sheet:
Smart snacking: An online planning tool



What is the study about?

We are doing a research study to find out more about tools to help people eat less unhealthy snacks. While many of us want to change the way we snack, this can be very hard. Often we make plans but have trouble sticking to them over long periods of time. This study will look at online tools that help people stick to their plans.

Who is carrying out the study?

We are from the School of Public Health at the University of Sydney. Our names are:

- Julie Ayre
- Carissa Bonner
- Robin Turner
- Erin Cvejic
- Kirsten McCaffery
- Stephen Walter

What will happen if I say that I want to be in the study?

You can decide if you want to take part in the study or not. Please read this sheet carefully so that you can make up your mind about whether you want to take part. Completing a question in the online survey is an indication of your consent to take part in the study.

You may stop completing the online survey at any point if you do not wish to continue, and we will not use your answers. You do not have to give a reason for not taking part. Once you have submitted your survey anonymously, your responses cannot be withdrawn.

If you decide that you want to be in our study, we will ask you to:

1. Complete questions online (for example, about the foods you eat and snacking habits)
2. Use the online planning tool to create a plan to help you eat less unhealthy snacks. We will ask you to follow the plan for 4 weeks. You will receive 3 reminder messages about your plan during that time.
3. Complete questions online about your snacking behaviour and your plan after 4 weeks.

Will anyone else know what I say in the study?

All of the information that we have about you from the study will be confidential. It will be stored in a safe place at the University of Sydney.

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We will write a report about the study and show it to other people but no one will know that you were in the study.

How long will the study take?

- The **first part** of the study will take about **20 minutes**.
- You will be asked to **try out your snacking plan** for **4 weeks**.
- The **second part** of the study (after 4 weeks) will take about **10 minutes**.

Are there any good things about being in the study?

This study may help you think more about the way that you snack. This is the first step to changing your eating patterns.

Are there any bad things about being in the study?

This study will take up some of your time, but we don't think it will be bad for you or cost you anything.

By giving your consent to take part in this study you are telling us that you:

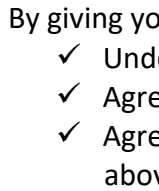
- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as described above.
- ✓ Agree to the use of your personal information for the research purposes described above.

What if I want more information about the study or my involvement in it?

You can contact the researcher Julie Ayre:

- **Call:** (02) 9351 7789
- **Email:** julie.ayre@sydney.edu.au.

What if I am not happy with the study or the people doing the study?



The ethical aspects of this study have been approved by the HREC of the University of Sydney [Project Number 2018/793].

If you are not happy with how we are doing the study or how we treat you, then you can:

- **Call** the university on +61 2 8627 8176 or
- Write an **email** to human.ethics@sydney.edu.au

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

Section / Item	Item Number	Description	
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	3 (available from ANZCTR)
Protocol version	3	Date and version identifier	3 (As shown in ANZCTR)
Funding	4	Sources and types of financial, material, and other support	24
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Role 24
	5b	Name and contact information for the trial sponsor	1
	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	24
	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)	N/A
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	4-6
	6b	Explanation for choice of comparators	4-5

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Objectives	7	Specific objectives or hypotheses	5-6
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)	6

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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	6-7
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)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-12
	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)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	12 (reminders emails)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
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	13-14
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)	8 (fig 1); 12
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	14-15
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	6-7; 14-15

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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	7
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	7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	18
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
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	12-14
	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	12 (reminders emails)
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	18-19

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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	16-18
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16-18
	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)	16
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	N/A
	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	15
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	Supp (PIS)
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research and ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
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)	N/A as not anticipated; however protocol updates can be as per trial

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			registry pg 3
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6-7, Supp PIS
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	18-19
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
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	19
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant level dataset, and statistical code	3, 18-19
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supp PIS
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

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*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.

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BMJ Open

Accounting for health literacy and intervention preferences when reducing unhealthy snacking: Protocol for an online randomized controlled trial

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Primary Subject Heading:	Public health
Secondary Subject Heading:	Diabetes and endocrinology
Keywords:	General diabetes < DIABETES & ENDOCRINOLOGY, PREVENTIVE MEDICINE, PUBLIC HEALTH

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Title

Accounting for health literacy and intervention preferences when reducing unhealthy snacking: Protocol for an online randomized controlled trial

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Abstract

Introduction

Health literacy describes the cognitive and social skills that individuals use to access, understand and act on health information. Health literacy interventions typically take the 'universal precautions approach' where all consumers are presented with simplified materials. Although this approach can improve knowledge and comprehension, its impact on complex behaviours is less clear. Systematic reviews also suggest health literacy interventions underutilise volitional strategies (such as planning) that play an important role in behaviour change. A recent study found volitional strategies may need to be tailored to the participant's health literacy. The current study aims to replicate these findings in a sample of people who have diabetes and/or are overweight or obese as measured by BMI, and to investigate the most effective method of allocating an action plan to a participant to reduce unhealthy snacking.

Methods and analysis

We plan to recruit approximately 2,400 participants at baseline. Participants will receive one of two alternative online action plans intended to reduce unhealthy snacking ('standard' action plan or 'literacy-sensitive' action plan). Participants will be randomised to a method of allocation to an action plan: 1) random allocation; 2) allocation by health literacy screening tool; or 3) allocation by participant selection. Primary outcome is self-reported serves of unhealthy snacks during the previous month. Multiple linear regression will evaluate the impact of health literacy on intervention effectiveness. The analysis will also identify independent contributions of each action plan, method of allocation, health literacy, and participant selections on unhealthy snacking at 4-week follow-up.

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Ethics and dissemination

This study was approved by the University of Sydney Human Research Ethics Committee [2017/793] and is registered with Australian New Zealand Clinical Trials Registry: ACTRN12618001409268p. Findings will be disseminated through peer-reviewed international journals, conferences and updates with collaborating public health bodies (Diabetes NSW & ACT, and Western Sydney Local Health District).

Article Summary

Strengths and limitations of this study

- The impact of literacy-sensitive design on the effectiveness of an action plan intervention to reduce unhealthy snacking in a sample of people with diverse health literacy levels will be evaluated.
- The analysis will isolate the effects of each action plan intervention (standard and literacy-sensitive) from the effects of allocation method (random, screened or choice), the participant's health literacy (as categorised using the screening tool) and the effect of providing a choice of interventions.
- Free-text plans in this study will undergo content analysis to assess the quality of plans created by people with higher and lower health literacy.
- The impact of assessing participant preference prior to random allocation to an intervention on outcomes will also be explored.
- This study uses a subjective outcome measure (self-reported monthly unhealthy snacking collected at a single time-point) rather than an objective measure (e.g. unhealthy snacking observed throughout the month-long period) or more frequently reported subjective measure, which may limit the study findings.

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Introduction

Health literacy describes the cognitive and social skills that enable individuals to access, understand and act on health information (1). Low health literacy is increasingly recognised as an important contributor to health inequality and is associated with increased hospitalization, mortality, prevalence of chronic disease and risk factors for health conditions (2). Low health literacy is common worldwide, with estimates ranging from 36 – 60% of the population in Australia, Europe and the US (3-5).

Current approaches to address health literacy issues have focused on providing all consumers, regardless of their health literacy level, with health information that is easy to process and understand (2, 6). Whilst this 'universal precautions approach' has been shown to improve health knowledge, it is less clear whether it is effective for improving complex behaviours such as healthy eating and increased physical activity (2, 7, 8). This may reflect the fact that health literacy guidelines and interventions place relatively little emphasis on strategies that promote action, such as planning, self-monitoring or problem solving (9-13). These kinds of strategies are increasingly recognised as key components of lifestyle interventions (14); furthermore, there has been little research investigating how they could be adapted for audiences with lower health literacy.

A recent randomized control trial (RCT) has investigated the effects of literacy-sensitive design on action plans to reduce unhealthy snacking behaviour (15). This design incorporated health literacy strategies (e.g. simple language) and separated the planning process into distinct steps to reduce cognitive demands. This 'literacy-sensitive' action plan was compared to action plan instructions that have been used in samples of the general population (16). The results from this study suggested that people with lower health literacy reported consuming

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fewer unhealthy snacks at follow-up when they had used the literacy-sensitive action plan, whereas people with higher health literacy reported consuming fewer unhealthy snacks using the 'standard' action plan (15).

The current study will build on these findings by evaluating the most effective way to determine the best action plan for participants. One obvious approach is to allocate an action plan based on a participant's health literacy score. Alternatively, participants could be asked to select the plan they would prefer to follow. Although allowing the participant to choose their plan might less accurately match a participant to an action plan that meets their health literacy needs, there are some potential additional advantages to this approach. For example, participants would be able to factor in other relevant aspects (such as their motivation to engage with the planning process) (17), and presenting participants with different options may also encourage greater satisfaction with the intervention (18). This is further supported by evidence that the effects of interventions in randomized controlled trials may be increased when participants receive their preferred intervention (19).

This study has three key aims. Firstly, this study aims to evaluate the impact of health literacy and a literacy-sensitive action plan on unhealthy snacking in a sample of people with type 2 diabetes and/or overweight or obese BMI. In doing so this study aims to replicate previous findings in a clinical sample (15).

The second aim is to evaluate how the *method of allocation* to either intervention (literacy-sensitive or standard action plan) affects the overall effectiveness of the intervention. Three methods of allocation will be evaluated: 1) random allocation to an action plan; 2) allocation to an action plan based on individual health literacy; or 3) allowing participants to choose which action plan they use. This study will employ a two-stage randomization (Rucker) design (20). This design allows estimation of the effects of each action plan on outcomes (the

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treatment effect), independent of the effects of a person receiving their preferred treatment (preference effect) and the effects of self-selection (selection effect). This is the only preference trial design that allows this delineation of all these effects (21).

The third aim is to evaluate whether assessment of participant preference for an intervention prior to random allocation influences the effectiveness of the intervention. This addresses an unanswered question in research on the effects of treatment preference on study outcomes i.e., does assessment of preference introduce a methodological artefact by increasing the salience of discrepancies between an individual's preferred and received treatments and in doing so, have a negative effect on intervention outcomes (21)?

We hypothesise that:

1. A literacy-sensitive action plan will be more effective at reducing unhealthy snacking for participants with lower health literacy, whereas the standard action plan will be more effective for participants with higher health literacy.

2. The intervention will be more effective at reducing unhealthy snacking for participants who are allocated an action plan using the health literacy screening tool compared to those who are asked to select their preferred action plan. Both of these allocation methods will be more effective than random allocation to an action plan.

3. Assessing preference will negatively impact plan effectiveness, an effect which will be greater for those who are randomised to the plan which is discordant with their preference.

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Methods and analysis

Study Design

The design is a three parallel-arm online RCT to test the effect of health literacy, type of action plan, and method of allocation to an action plan on self-reported unhealthy snacking behaviour. The three methods of allocation are 1) random 2) use of a health literacy screening tool to allocate participants one of the two action plans ('screened' arm) and 3) participant choice of action plan ('choice' arm). This study will also evaluate whether the process of assessing preference for a particular action plan prior to randomisation will have an impact on subsequent self-reported snacking behaviour. A schematic representation of the study design is shown in Figure 1.

Participants and recruitment

The proposed study will seek to recruit 2,352 Australian participants with type 2 diabetes. Participants will be recruited through an online market research company, Dynata, which has a pool of approximately 10,000 Australians with type 2 diabetes. This sample will be supplemented with additional participants from Dynata who have self-reported height and weight corresponding to an overweight or obese BMI (i.e., BMI $\geq$ 25 kg/m^2). Participants will be eligible to participate if they are registered with DynataI's Australian registry, are over 18 years of age (adult population), and self-report that they have type 2 diabetes or self-report a height and weight that correspond to overweight or obese BMI. Participants will be excluded if they do not speak English. Participants will not be excluded on the basis of their snacking behaviour. Recruitment commenced February 14th, 2019.

Participants who click the link received from Dynata will be presented with a brief introduction to the study and a link to the Participant Information Sheet (see Supplementary File 1). Informed consent will be indicated by completion of the online survey, as outlined in

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the Participant Information Sheet. On the next page, participants then begin the baseline survey.

Patient and public involvement

Patients and public were not directly involved in development of the research question, however, consumer health representatives living with type 2 diabetes were consulted for feedback at multiple stages of intervention and study development, including: intervention instructions, the appropriateness of the literacy sensitive plans, and the ease with which feedback at follow-up could be communicated. Participants in the trial are able to indicate if they are interested in receiving a lay summary of the study results which will be disseminated through email by Dynata (further maintaining participants anonymity). We will also assess participant burden and acceptability using the pilot data. Lastly, participants will be able to provide feedback on the perceived burden of the intervention using free text fields during the follow-up survey.

Participant allocation

After completing baseline measures participants will be randomised to one of three allocation methods using the 'Survey Flow' and 'Randomiser' functions included in the survey platform (Qualtrics) (Figure 1). The 'Randomiser' is based on the Mersenne Twister, a pseudorandom number generator. This allocation method will determine how the planning tool (either literacy-sensitive or standard) is assigned to the participant. Participants in the random arm will be unaware of their allocation method. At baseline, only the participants in the choice arm and those who are randomised to assess prior preference in the random arm will be aware of the two different tool versions. Participants in the screened arm will be aware that there is more than one tool available.

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[Figure 1 here]

Figure 1: Anticipated participant recruitment and attrition to achieve sufficient sample size

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Allocation method

1. **Random (Arm A):** Participants randomised to the 'random' arm will be further randomised to either 1) assess their prior preferences (i.e. their preferred action plan; Arm A1), and then randomised to the standard or literacy-sensitive action plan; or 2) randomised to the standard or literacy-sensitive action plan without assessment of prior preferences (Arm A2; Figure 1). Prior preference will be measured using the same format as in the 'participant choice' arm (Arm C) with additional text stating that participants may not receive their preferred tool.
2. **Screened (Arm B)**: Allocation is based on assessment of health literacy using the Newest Vital Sign (NVS) measure (22). The literacy-sensitive action plan will be allocated to those scoring less than 4 (indicative of inadequate health literacy), and the standard action plan will be allocated to the remaining participants. Participants will be told that, based on their responses, the researchers have selected an action plan tool that is most suitable for them.
3. **Choice (Arm C)**: Participants will be provided with a brief description of the action plans and select the plan they want to use. Order of presentation of the two plans is randomised. In the first instance, participants have the option of selecting 'Unsure' to allow for undecided participants. Participants will then be presented with an alternative description of the study and asked again to make a choice. Participants will be informed that if they select 'Unsure' again, the researchers will select a plan for them. In doing so, participants will be randomised to an action plan as per Rucker protocol (20).

Action plan interventions

Either a literacy-sensitive or standard action plan will be allocated to participants. The text used in each tool is presented below:

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Literacy-sensitive action plan ("Smart Snacking 101 (basic)"): This commences with the text: "We want you to plan how you will change your unhealthy snacking behaviour each day because forming plans has been shown to improve snacking habits". The intervention consists of 4 steps that guide the participant through the process of developing an appropriate plan (also shown in Figure 2):

1. Step 1: Sometimes we snack because we are hungry, but there are lots of other reasons. Think about your snacks in the last week. Below is a list of 'snack moments.' These are times when people tend to choose unhealthy snacks or eat too much. Choose 3 snack moments from the list that happened to you the most often in the last week. [Participants selects from list of snack moments].
2. Step 2: Below are your top 3 snack moments. Some snack moments will be more important than others. Choose the 1 that you would be happiest to change. [Participant chooses from 3 previously selected snack moments]
3. Step 3: Great! Your most important snack moment was snacking because you are [example snack moment: bored]. The last step is to come up with a plan! Choose the solution that you think will work best for you. Drag it into the space on the right. [Participants selects from list of solutions]
4. Step 4: Imagine how your plan might feel. [examples of scenarios when this might happen]. The final step is to make sure the plan is realistic. How hard do you think it will be to do this plan for the next month [Slider options range from very easy (1) to very hard (10). If the participant selects a number greater than or equal to 7 they will be prompted to revise the plan]

[Figure 2 here]

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Figure 2: Mobile screenshots from *literacy-sensitive action plan*. From left to right: a) Step 1: Selecting top 3 snacking scenarios; b) Step 2: Selecting 1 key scenario; c) Step 3: Selecting a solution; d) Step 4: Imagining the plan

Standard action plan ("Smart Snacking Pro (advanced)"): Participants receive the following instructions: "We want you to plan how you will change your unhealthy snacking behaviour each day, because forming plans has been shown to improve snacking habits. You are free to choose how you do this but we want you to formulate your plans in as much detail as possible. Pay attention to the situations in which you will implement (carry out) these plans. Focus on situations when you are not hungry but find yourself snacking. Please enter your situations and your plans below."

After completing either action plan participants will be presented with their plan for a final time and instructed to write down, take a screenshot or make a copy of it. Participants will also be asked to confirm that they have a copy of the plan. We have incorporated behaviour change techniques into each intervention. These are described in detail in the Supplementary File 2.

Baseline and follow-up surveys

At baseline participants will complete demographic questions and measures of health literacy. They will then receive information about general reasons for reducing unhealthy snacking and a definition of unhealthy snacks. Participants then complete measures of snacking behaviour, habit strength (concerning consumption of unhealthy snacks), and intentions to reduce unhealthy snacking. Intention to reduce unhealthy snacking will be measured again, immediately after creating the plan. Participants will be emailed a reminder of their personal

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plan at baseline (within the first week), and before then end of the 2nd and 3rd weeks to increase compliance and retention. Participants will complete a follow-up survey after 4 weeks. The follow-up survey consists of the same description of reasons to reduce unhealthy snacking and definition, followed by measures of snacking behaviour, habit strength and intention. Action control will also be measured in the follow-up survey.

Measures

Screening measures

Prior to beginning the survey, participants will be asked to indicate whether they have type 2 diabetes, and to provide their height (cm or feet and inches) and weight (kg).

Demographic measures

Participants will be asked to complete questions about their age, employment status, highest level of educational attainment, and, if they report having diabetes, years since diagnosis and whether or not they use insulin.

Health literacy

Health literacy will be measured using the Newest Vital Sign (NVS)(22), a 6-item measure of functional health literacy, and a single-item literacy screener (23). NVS scores of 0-1 indicate a high likelihood of limited healthy literacy, scores of 2-3 indicate the possibility of limited health literacy and scores of 4-6 indicate adequate health literacy.

Need for cognition

Need for cognition describes the extent that an individual engages in and enjoys cognitively effortful activities (i.e. activities that require a lot of thinking) (24). Three items on a 7-point likert scale (strongly disagree to strongly agree) will assess the participant's need for cognition (25).

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Primary outcome

Snack scores (previous month)

Snacking scores will be measured using a validated 7-item measure based on a diet score developed by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) (26). Items are drawn from the 'discretionary foods' category which the Australian Guidelines to Healthy Eating define as foods 'not considered necessary for a healthy diet'. Alcohol was excluded from the assessment in this study as the focus is on 'snacks.' Participants answer how many serves of unhealthy snacks they ate in the past month. Participants can answer according to the number of serves per day, week or month. Average weekly serves of unhealthy snacks will be calculated from these scores. Although electronic diaries might overcome some limitations of once-off measures of snacking behaviour such as that described above, electronic diaries were unavailable at the time of study development due to the budget and technical constraints. This approach chosen also reduces participant burden and minimises the risk of missing data.

Secondary outcomes

Perceived unhealthy/healthy snacking (previous week)

Two items, each on a 7-point Likert scale will assess perceived extent of healthy and unhealthy snacking in the previous week, respectively. Healthy snacks are described to participants as those that are low in kilojoules, fat, salt and sugars. Unhealthy snacks are described as high in kilojoules, fat, salt and sugars. Examples of healthy and unhealthy snacks are provided.

Intention, habit strength and action control

The measure of intention consists of 3 items that ask about the participant's intention to reduce unhealthy snacking (27, 28). Habit strength will be assessed using the 12-item self-

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report habit strength index (29), and action control will be assessed using a 6-item measure (30). Responses to each item are recorded on 7-point Likert scales (strongly disagree to strongly agree).

Difficulty using the planning tool

A single item will ask participants to rate how hard it was to use the planning tool (1=not at all hard, 5=extremely hard).

Preferred action plan at follow-up

At follow-up, participants will be reminded of the name and logo used for their plan. Participants will be shown an image slider that contains screenshots from the other action plan. Participants will then be asked: "If you were given the choice, which action plan would you prefer to use next time?"

Sample size

The proposed study will seek to analyse a sample of 2,000 Australian participants at follow-up with high BMI (overweight/obese) and/or type 2 diabetes. At baseline participants will be randomised at a ratio of 2:1:1 to each allocation method arm, such that there are a total of 1,000 participants in the random arm (who will then be evenly randomised to assess or not assess their preference for a particular action plan before they are ultimately randomised to an action plan), and 500 in the two remaining allocation method arms (the screened and choice arms). With a two sided alpha of 0.05 and power of 80%, a sample of this size will allow us to detect a small main effect of $f = 0.08$ in a univariate ANOVA comparing the three allocation method arms and in a univariate ANOVA comparing the two prior-preference assessment arms; this corresponds to a minimum pairwise difference between the two most extreme mean values of approximately 0.18 standard deviations. Estimates of effect size are based on the outcome of previous work exploring the effects of action plans on unhealthy snacking (15).

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Based on our previous studies recruiting through this provider, we anticipate an attrition rate no greater than 15% by one month follow-up. Therefore, we estimate a total of 2, 352 should be recruited at baseline to ensure sufficient sample size for analysis.

A sample of this size will also ensure that there is at least 80% power for secondary analysis conducted to estimate treatment and preference effects (20, 31) with a treatment effect between the two interventions (literacy-sensitive and standard planning tools) as small as 0.25 standard deviations (estimated as 5 snacks per month based on previous findings (15)), and a preference effect, comparing those who received their preferred tool to those who did not, as small as 0.35 standard deviations (approximately 7 snacks per month). This assumes that approximately equal proportions of participants will choose the literacy-sensitive and standard planning tools in the choice arm, and that there will be approximately equal proportions of participants allocated to each of these interventions in the screened arm.

Piloting

The intervention will be piloted with 200 participants to check that approximately equal numbers of participants allocated to the choice condition select each of the interventions. If required, sample size estimates will be adjusted to ensure that the study is sufficiently powered. Piloting will also allow us to assess participant burden and intervention acceptability.

Analysis:

Follow-up outcome measures for participants who do not complete the follow-up survey will be estimated for worst-case (no change in snacking score) and best-case scenarios (average-change in snack score). These estimates will be incorporated as an intention-to-treat analysis. Baseline characteristics of completers and non-completers will be compared to assess bias and generalisability.

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Confirmatory analysis

A confirmatory analysis will replicate the analysis previously reported (15) to examine if the treatment effect is modified by health literacy. Multiple linear regression models including an intervention group × health literacy (NVS score) interaction term will be used to predict follow-up snacking scores and perceived difficulty using the plan. Important correlates of health literacy (age, level of education, language spoken at home) (2), diabetes status and baseline snacking will be controlled for in the model. NVS scores will be examined both continuously and categorically (i.e., inadequate vs. adequate health literacy).

Assessment of prior preference analysis

For participants in the random arm of the study, participants whose action plan preference was assessed prior to randomisation to an intervention will be compared to those whose preference was not assessed. Multiple linear regression (controlling for health literacy, age, level of education, language spoken at home and baseline snacking) will evaluate the effect of preference assessment on unhealthy snacking behaviour. For participants who provided a preference, an additional multiple linear regression will evaluate the effect of participants receiving their preferred intervention compared to those not receiving their preferred intervention on unhealthy snacking behaviour.

Analysis of effects of allocation method

The primary analysis will use regression to test for a difference in self-reported unhealthy snacking between the three randomised arms (random, screened, and choice) whilst adjusting for any effect of diabetes status. An adjusted model will also be constructed to allow for any baseline imbalances in the potential confounders including age, English as a second language, level of education. The analysis will be repeated on the secondary outcomes of perceived unhealthy snacking in the previous week, snacks consumed the previous day, difficulty using

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the planning tool, action control, and habit strength with similar adjustment for diabetes status and any baseline imbalances. A sub-analysis will also be conducted on participants with and without type 2 diabetes.

An appropriate analysis that uses the available preference information will be used to estimate treatment, preference and selection effects for the primary outcome (32). The treatment effect compares the efficacy of the health literate action plan with the standard action plan in the random arm. The preference effect and selection effects are estimated using the random and choice arms. The preference effect measures the difference in self-reported unhealthy snacking for those who received their preferred action plan compared to those who did not receive their preferred action plan. The selection effect measures the difference between those who would select the literacy-sensitive intervention with those who would select the standard intervention regardless of which intervention they received. Secondary analyses will adjust for diabetes status, and baseline imbalances in potential confounders including age, English as a second language, level of education. Data from participants in the screened arm will also be analysed in this manner, producing estimates analogous to the preference and selection effects.

These effects will also be estimated for the secondary outcomes of perceived unhealthy snacking in the previous week, snacks consumed the previous day, difficulty using the planning tool, action control, and habit strength with similar adjustment for diabetes status and any baseline imbalances.

Bootstrapping, by taking repeated random samples with replacement, will be used to estimate the difference between the preference effect (estimated using choice arm) and an analogous effect estimated using the screened arm, as well as the difference between the selection effect (estimated using the choice arm) and an analogous effect estimated using the screened arm.

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Bootstrapping will also be used to estimate the confidence intervals for non-continuous outcome measures. The bootstrapping is necessary, as the variances for the estimated differences and non-continuous outcomes have not been derived previously (33).

Additional analysis

Two researchers will also independently code standard action plans to indicate the extent that participants followed standard action plan instructions (that is, provided at least one 'situation', and one 'plan') and the extent that plans differed from the pre-determined options presented in the literacy-sensitive action plans (for example, situations or solutions that did not correspond to options listed in the literacy-sensitive action plan, or strategies that fell outside of the "If-then" construction. The latter may include, for example, making sure healthy snacks are prepared in advance, or refraining from buying certain foods at the supermarket). Coders will be blind to the health literacy level of participants. Any disagreements will be systematically resolved through discussion. Results from this content analysis will also inform a secondary analysis of the impact of allocation method and action plan on snacking scores.

Data management

De-identified data will be captured electronically on the secure Qualtrics server. Data will be stored securely in de-identified form, with a unique participant ID to link responses from the baseline and follow-up surveys. In all forms of dissemination, only de-identified data will be presented as group means and differences to maintain the anonymity of participants. In line with National Health and Medical Research Council (NHMRC) recommendations, and University of Sydney policies, all data will be kept for a minimum 5 years.

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Ethics and dissemination

This study was approved by the University of Sydney Human Research Ethics Committee [2017/793]. The interventions used in this study are practical; they can be easily incorporated into existing self-management practices, particularly with the use of online technologies, and are low in cost. Ascertaining an effective way to tailor planning tools to health literacy level (that is, allowing the participant to choose by employing a screening tool) will provide valuable information for implementation in apps that target people with varying health literacy levels. Findings from this study will be disseminated through peer-reviewed publication and national and international conference presentations. Findings will also be disseminated through community and research partnerships with groups such as Western Sydney Diabetes.

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Authors' contributions

Conceptualisation, methodology, writing – review and editing: JA, CB, EC, RT, SW, KM

Investigation, project administration: JA

Writing – original draft preparation: JA, EC, RT

Software: RT

Supervision: EC, CB, KM

Funding acquisition: CB, JA, RT, KM

Data availability statement

There are no data in this work. No data are as yet available for this study as recruitment is currently under way.

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Competing interests statement

Authors have no competing interests.

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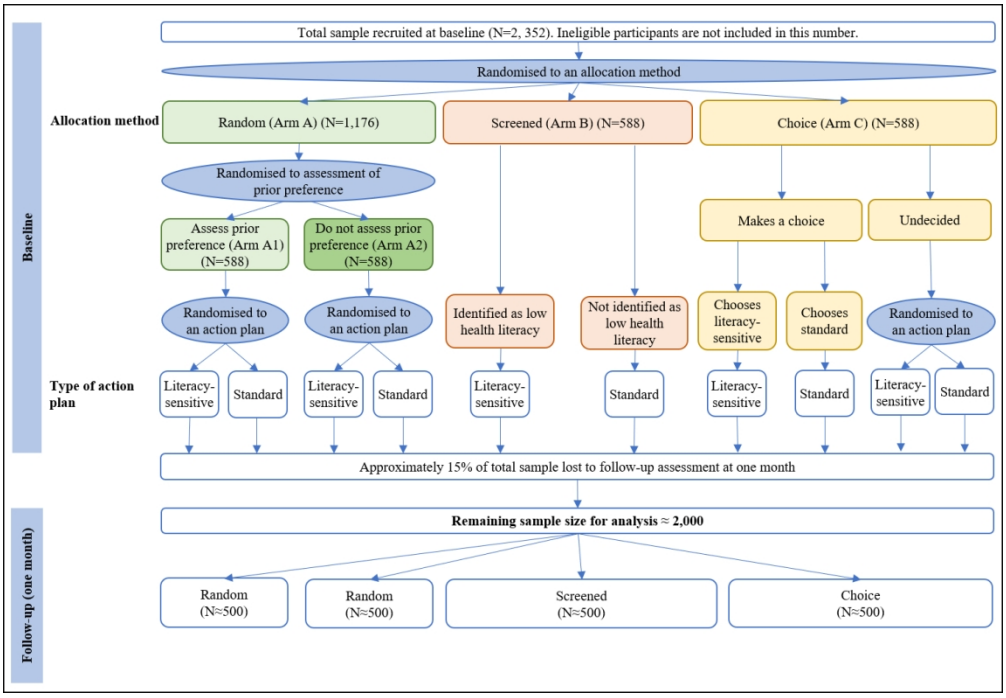

Figure 1: Anticipated participant recruitment and attrition to achieve sufficient sample size

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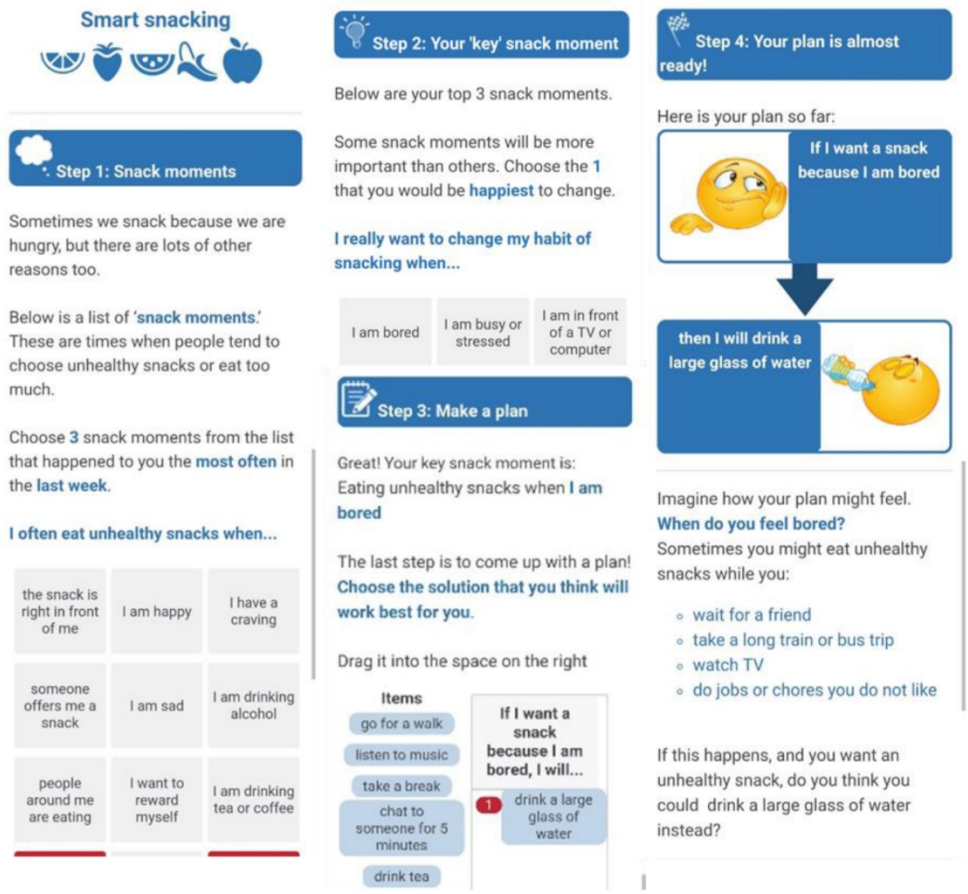

Figure 2: Mobile screenshots from literacy-sensitive action plan. From left to right: a) Step 1: Selecting top 3 snacking scenarios; b) Step 2: Selecting 1 key scenario; c) Step 3: Selecting a solution; d) Step 4: Imagining the plan

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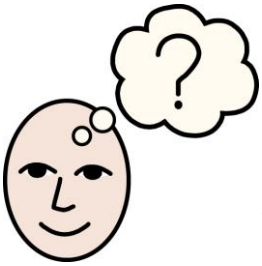
THE UNIVERSITY OF SYDNEY

Study Information Sheet:
Smart snacking: An online planning tool



What is the study about?

We are doing a research study to find out more about tools to help people eat less unhealthy snacks. While many of us want to change the way we snack, this can be very hard. Often we make plans but have trouble sticking to them over long periods of time. This study will look at online tools that help people stick to their plans.

Who is carrying out the study?

We are from the School of Public Health at the University of Sydney. Our names are:

- Julie Ayre
- Carissa Bonner
- Robin Turner
- Erin Cvejic
- Kirsten McCaffery
- Stephen Walter

What will happen if I say that I want to be in the study?

You can decide if you want to take part in the study or not. Please read this sheet carefully so that you can make up your mind about whether you want to take part. Completing a question in the online survey is an indication of your consent to take part in the study.

You may stop completing the online survey at any point if you do not wish to continue, and we will not use your answers. You do not have to give a reason for not taking part. Once you have submitted your survey anonymously, your responses cannot be withdrawn.

If you decide that you want to be in our study, we will ask you to:

1. Complete questions online (for example, about the foods you eat and snacking habits)
2. Use the online planning tool to create a plan to help you eat less unhealthy snacks. We will ask you to follow the plan for 4 weeks. You will receive 3 reminder messages about your plan during that time.
3. Complete questions online about your snacking behaviour and your plan after 4 weeks.

Will anyone else know what I say in the study?

All of the information that we have about you from the study will be confidential. It will be stored in a safe place at the University of Sydney.

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We will write a report about the study and show it to other people but no one will know that you were in the study.

How long will the study take?

- The **first part** of the study will take about **20 minutes**.
- You will be asked to **try out your snacking plan** for **4 weeks**.
- The **second part** of the study (after 4 weeks) will take about **10 minutes**.

Are there any good things about being in the study?

This study may help you think more about the way that you snack. This is the first step to changing your eating patterns.

Are there any bad things about being in the study?

This study will take up some of your time, but we don't think it will be bad for you or cost you anything.

By giving your consent to take part in this study you are telling us that you:

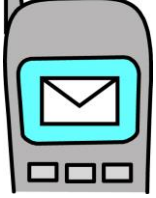
- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as described above.
- ✓ Agree to the use of your personal information for the research purposes described above.

What if I want more information about the study or my involvement in it?

You can contact the researcher Julie Ayre:

- **Call:** (02) 9351 7789
- **Email:** julie.ayre@sydney.edu.au.

What if I am not happy with the study or the people doing the study?



The ethical aspects of this study have been approved by the HREC of the University of Sydney [Project Number 2018/793].

If you are not happy with how we are doing the study or how we treat you, then you can:

- **Call** the university on +61 2 8627 8176 or
- Write an **email** to human.ethics@sydney.edu.au

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Supplementary Material: Behaviour Change Techniques present in intervention

Supplementary Table 1: Behaviour Change Techniques present in intervention

Intervention	Intervention feature	Behaviour change technique
Literacy-sensitive	The text 'forming plans has shown to improve snacking habits'	Credible source
	Identifying situations for unhealthy snacking	Problem solving
	Identifying an alternative behaviour to enact in snacking situation	Behaviour substitution
	Generation of plan (with images) to reduce unhealthy snacking	Action planning
	Instruction to imagine enacting the plan	Mental rehearsal of a successful performance
	Reminder emails	Prompts/cues
Standard	The text 'forming plans has shown to improve snacking habits'	Credible source
	Identifying situations for unhealthy snacking	Problem solving
	Generation of plan to reduce unhealthy snacking	Action planning
	Reminder emails	Prompts/cues

Note: **Behaviour Change Techniques are based on the Behaviour Change Technique Taxonomy v1 (Michie et al., 2013)**

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

Section / Item	Item Number	Description	
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	3 (available from ANZCTR)
Protocol version	3	Date and version identifier	3 (As shown in ANZCTR)
Funding	4	Sources and types of financial, material, and other support	24
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Role 24
	5b	Name and contact information for the trial sponsor	1
	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	24
	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)	N/A
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	4-6
	6b	Explanation for choice of comparators	4-5

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Objectives	7	Specific objectives or hypotheses	5-6
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)	6

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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	6-7
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)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-12
	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)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	12 (reminders emails)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
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	13-14
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)	8 (fig 1); 12
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	14-15
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	6-7; 14-15

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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	7
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	7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	18
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
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	12-14
	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	12 (reminders emails)
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	18-19

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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	16-18
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16-18
	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)	16
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	N/A
	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	15
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	Supp (PIS)
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research and ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
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)	N/A as not anticipated; however protocol updates can be as per trial

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			registry pg 3
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6-7, Supp PIS
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	18-19
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
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	19
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant level dataset, and statistical code	3, 18-19
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supp PIS
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

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Title

Accounting for health literacy and intervention preferences when reducing unhealthy snacking: Protocol for an online randomized controlled trial

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Abstract

Introduction

Health literacy describes the cognitive and social skills that individuals use to access, understand and act on health information. Health literacy interventions typically take the 'universal precautions approach' where all consumers are presented with simplified materials. Although this approach can improve knowledge and comprehension, its impact on complex behaviours is less clear. Systematic reviews also suggest health literacy interventions underutilise volitional strategies (such as planning) that play an important role in behaviour change. A recent study found volitional strategies may need to be tailored to the participant's health literacy. The current study aims to replicate these findings in a sample of people who have diabetes and/or are overweight or obese as measured by BMI, and to investigate the most effective method of allocating an action plan to a participant to reduce unhealthy snacking.

Methods and analysis

We plan to recruit approximately 2,400 participants at baseline. Participants will receive one of two alternative online action plans intended to reduce unhealthy snacking ('standard' action plan or 'literacy-sensitive' action plan). Participants will be randomised to a method of allocation to an action plan: 1) random allocation; 2) allocation by health literacy screening tool; or 3) allocation by participant selection. Primary outcome is self-reported serves of unhealthy snacks during the previous month. Multiple linear regression will evaluate the impact of health literacy on intervention effectiveness. The analysis will also identify independent contributions of each action plan, method of allocation, health literacy, and participant selections on unhealthy snacking at 4-week follow-up.

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Ethics and dissemination

This study was approved by the University of Sydney Human Research Ethics Committee [2017/793] and is registered with Australian New Zealand Clinical Trials Registry: ACTRN12618001409268p. Findings will be disseminated through peer-reviewed international journals, conferences and updates with collaborating public health bodies (Diabetes NSW & ACT, and Western Sydney Local Health District).

Article Summary

Strengths and limitations of this study

- The impact of literacy-sensitive design on the effectiveness of an action plan intervention to reduce unhealthy snacking in a sample of people with diverse health literacy levels will be evaluated.
- The analysis will isolate the effects of each action plan intervention (standard and literacy-sensitive) from the effects of allocation method (random, screened or choice), the participant's health literacy (as categorised using the screening tool) and the effect of providing a choice of interventions.
- Free-text plans in this study will undergo content analysis to assess the quality of plans created by people with higher and lower health literacy.
- The impact of assessing participant preference prior to random allocation to an intervention on outcomes will also be explored.
- This study uses a subjective outcome measure (self-reported monthly unhealthy snacking collected at a single time-point) rather than an objective measure (e.g. unhealthy snacking observed throughout the month-long period) or more frequently

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reported subjective measure, and has a relatively short follow-up period; these aspects may limit the study findings.

Introduction

Health literacy describes the cognitive and social skills that enable individuals to access, understand and act on health information (1). Low health literacy is increasingly recognised as an important contributor to health inequality and is associated with increased hospitalization, mortality, prevalence of chronic disease and risk factors for health conditions (2). Low health literacy is common worldwide, with estimates ranging from 36 – 60% of the population in Australia, Europe and the US (3-5).

Current approaches to address health literacy issues have focused on providing all consumers, regardless of their health literacy level, with health information that is easy to process and understand (2, 6). Whilst this 'universal precautions approach' has been shown to improve health knowledge, it is less clear whether it is effective for improving complex behaviours such as healthy eating and increased physical activity (2, 7, 8). This may reflect the fact that health literacy guidelines and interventions place relatively little emphasis on strategies that promote action, such as planning, self-monitoring or problem solving (9-13). These kinds of strategies are increasingly recognised as key components of lifestyle interventions (14); furthermore, there has been little research investigating how they could be adapted for audiences with lower health literacy.

A recent randomized control trial (RCT) has investigated the effects of literacy-sensitive design on action plans to reduce unhealthy snacking behaviour (15). This design incorporated health literacy strategies (e.g. simple language) and separated the planning process into

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distinct steps to reduce cognitive demands. This 'literacy-sensitive' action plan was compared to action plan instructions that have been used in samples of the general population (16). The results from this study suggested that people with lower health literacy reported consuming fewer unhealthy snacks at follow-up when they had used the literacy-sensitive action plan, whereas people with higher health literacy reported consuming fewer unhealthy snacks using the 'standard' action plan (15).

The current study will build on these findings by evaluating the most effective way to determine the best action plan for participants. One obvious approach is to allocate an action plan based on a participant's health literacy score. Alternatively, participants could be asked to select the plan they would prefer to follow. Although allowing the participant to choose their plan might less accurately match a participant to an action plan that meets their health literacy needs, there are some potential additional advantages to this approach. For example, participants would be able to factor in other relevant aspects (such as their motivation to engage with the planning process) (17), and presenting participants with different options may also encourage greater satisfaction with the intervention (18). This is further supported by evidence that the effects of interventions in randomized controlled trials may be increased when participants receive their preferred intervention (19).

This study has three key aims. Firstly, this study aims to evaluate the impact of health literacy and a literacy-sensitive action plan on unhealthy snacking in a sample of people with type 2 diabetes and/or overweight or obese BMI. In doing so this study aims to replicate previous findings in a clinical sample (15). Unhealthy snacking in this study includes consumption of discretionary foods as described in the Australian Guidelines to Healthy Eating (20). For the purposes of this study, this included sugar-sweetened beverages and excluded alcoholic beverages.

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The second aim is to evaluate how the *method of allocation* to either intervention (literacy-sensitive or standard action plan) affects the overall effectiveness of the intervention. Three methods of allocation will be evaluated: 1) random allocation to an action plan; 2) allocation to an action plan based on individual health literacy; or 3) allowing participants to choose which action plan they use. This study will employ a two-stage randomization (Rucker) design (21). This design allows estimation of the effects of each action plan on outcomes (the treatment effect), independent of the effects of a person receiving their preferred treatment (preference effect) and the effects of self-selection (selection effect). This is the only preference trial design that allows this delineation of all these effects (22).

The third aim is to evaluate whether assessment of participant preference for an intervention prior to random allocation influences the effectiveness of the intervention. This addresses an unanswered question in research on the effects of treatment preference on study outcomes i.e., does assessment of preference introduce a methodological artefact by increasing the salience of discrepancies between an individual's preferred and received treatments and in doing so, have a negative effect on intervention outcomes (22)?

We hypothesise that:

1. A literacy-sensitive action plan will be more effective at reducing unhealthy snacking for participants with lower health literacy, whereas the standard action plan will be more effective for participants with higher health literacy.

2. The intervention will be more effective at reducing unhealthy snacking for participants who are allocated an action plan using the health literacy screening tool compared to those who are asked to select their preferred action plan. Both of these allocation methods will be more effective than random allocation to an action plan.

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3. Assessing preference will negatively impact plan effectiveness, an effect which will be greater for those who are randomised to the plan which is discordant with their preference.

Methods and analysis

Study Design

The design is a three parallel-arm online RCT to test the effect of health literacy, type of action plan, and method of allocation to an action plan on self-reported unhealthy snacking behaviour. The three methods of allocation are 1) random 2) use of a health literacy screening tool to allocate participants one of the two action plans ('screened' arm) and 3) participant choice of action plan ('choice' arm). This study will also evaluate whether the process of assessing preference for a particular action plan prior to randomisation will have an impact on subsequent self-reported snacking behaviour. A schematic representation of the study design is shown in Figure 1.

Participants and recruitment

The proposed study will seek to recruit 2,352 Australian participants with type 2 diabetes. Participants will be recruited through an online market research company, Dynata, which has a pool of approximately 10,000 Australians with type 2 diabetes. This sample will be supplemented with additional participants from Dynata who have self-reported height and weight corresponding to an overweight or obese BMI (i.e., BMI $\geq$ 25 kg/m^2). Participants will be eligible to participate if they are registered with DynataI's Australian registry, are over 18 years of age (adult population), and self-report that they have type 2 diabetes or self-report a height and weight that correspond to overweight or obese BMI. Participants will be excluded if they do not speak English. Participants will not be excluded on the basis of their snacking behaviour. Recruitment commenced February 14th, 2019.

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Participants who click the link received from Dynata will be presented with a brief introduction to the study and a link to the Participant Information Sheet (see Supplementary File 1). Informed consent will be indicated by completion of the online survey, as outlined in the Participant Information Sheet. On the next page, participants then begin the baseline survey.

Patient and public involvement

Patients and public were not directly involved in development of the research question, however, consumer health representatives living with type 2 diabetes were consulted for feedback at multiple stages of intervention and study development, including: intervention instructions, the appropriateness of the literacy sensitive plans, and the ease with which feedback at follow-up could be communicated. Participants in the trial are able to indicate if they are interested in receiving a lay summary of the study results which will be disseminated through email by Dynata (further maintaining participants anonymity). We will also assess participant burden and acceptability using the pilot data. Lastly, participants will be able to provide feedback on the perceived burden of the intervention using free text fields during the follow-up survey.

Participant allocation

After completing baseline measures participants will be randomised to one of three allocation methods using the 'Survey Flow' and 'Randomiser' functions included in the survey platform (Qualtrics) (Figure 1). The 'Randomiser' is based on the Mersenne Twister, a pseudorandom number generator. This allocation method will determine how the planning tool (either literacy-sensitive or standard) is assigned to the participant. Participants in the random arm will be unaware of their allocation method. At baseline, only the participants in the choice arm and those who are randomised to assess prior preference in the random arm will be aware

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of the two different tool versions. Participants in the screened arm will be aware that there is more than one tool available.

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[Figure 1 here]

Figure 1: Anticipated participant recruitment and attrition to achieve sufficient sample size

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Allocation method

1. **Random (Arm A):** Participants randomised to the 'random' arm will be further randomised to either 1) assess their prior preferences (i.e. their preferred action plan; Arm A1), and then randomised to the standard or literacy-sensitive action plan; or 2) randomised to the standard or literacy-sensitive action plan without assessment of prior preferences (Arm A2; Figure 1). Prior preference will be measured using the same format as in the 'participant choice' arm (Arm C) with additional text stating that participants may not receive their preferred tool.
2. **Screened (Arm B)**: Allocation is based on assessment of health literacy using the Newest Vital Sign (NVS) measure (23). The literacy-sensitive action plan will be allocated to those scoring less than 4 (indicative of inadequate health literacy), and the standard action plan will be allocated to the remaining participants. Participants will be told that, based on their responses, the researchers have selected an action plan tool that is most suitable for them.
3. **Choice (Arm C)**: Participants will be provided with a brief description of the action plans and select the plan they want to use. The literacy-sensitive intervention is described in simple language whereas the standard intervention is described using more complex words (e.g. 'tailored plan that suits your specific situation' vs 'simple plan using common ways to eat less snacks'). It is anticipated that the difference in language complexity will help participants select the most appropriate tool for their health literacy level by giving an indirect indication of the relative level of cognitive effort required, in addition to the explicit descriptions which describe the relatively greater cognitive effort required in the standard plan. Order of presentation of the two plans is randomised. In the first instance, participants have the option of selecting 'Unsure' to allow for undecided

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participants. Participants will then be presented with an alternative description of the study and asked again to make a choice. Participants will be informed that if they select 'Unsure' again, the researchers will select a plan for them. In doing so, participants will be randomised to an action plan as per Rucker protocol (21).

Action plan interventions

Either a literacy-sensitive or standard action plan will be allocated to participants. The text used in each tool is presented below:

Literacy-sensitive action plan ("Smart Snacking 101 (basic)"): This commences with the text: "We want you to plan how you will change your unhealthy snacking behaviour each day because forming plans has been shown to improve snacking habits". The intervention consists of 4 steps that guide the participant through the process of developing an appropriate plan (also shown in Figure 2):

1. Step 1: Sometimes we snack because we are hungry, but there are lots of other reasons. Think about your snacks in the last week. Below is a list of 'snack moments.' These are times when people tend to choose unhealthy snacks or eat too much. Choose 3 snack moments from the list that happened to you the most often in the last week. [Participants selects from list of snack moments].
2. Step 2: Below are your top 3 snack moments. Some snack moments will be more important than others. Choose the 1 that you would be happiest to change. [Participant chooses from 3 previously selected snack moments]
3. Step 3: Great! Your most important snack moment was snacking because you are [example snack moment: bored]. The last step is to come up with a plan! Choose the solution that you think will work best for you. Drag it into the space on the right. [Participants selects from list of solutions]

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4. Step 4: Imagine how your plan might feel. [examples of scenarios when this might happen]. The final step is to make sure the plan is realistic. How hard do you think it will be to do this plan for the next month [Slider options range from very easy (1) to very hard (10). If the participant selects a number greater than or equal to 7 they will be prompted to revise the plan]

[Figure 2 here]

Figure 2: Mobile screenshots from *literacy-sensitive action plan*. From left to right: a) Step 1: Selecting top 3 snacking scenarios; b) Step 2: Selecting 1 key scenario; c) Step 3: Selecting a solution; d) Step 4: Imagining the plan

Standard action plan ("Smart Snacking Pro (advanced)"): Participants receive the following instructions: "We want you to plan how you will change your unhealthy snacking behaviour each day, because forming plans has been shown to improve snacking habits. You are free to choose how you do this but we want you to formulate your plans in as much detail as possible. Pay attention to the situations in which you will implement (carry out) these plans. Focus on situations when you are not hungry but find yourself snacking. Please enter your situations and your plans below."

After completing either action plan participants will be presented with their plan for a final time and instructed to write down, take a screenshot or make a copy of it. Participants will also be asked to confirm that they have a copy of the plan. We have incorporated behaviour change techniques into each intervention. These are described in detail in the Supplementary File 2.

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Baseline and follow-up surveys

At baseline participants will complete demographic questions and measures of health literacy. They will then receive information about general reasons for reducing *unhealthy* snacking (such as avoiding weight gain), reasons for 'smart snacking' (i.e. choosing healthy snacks), definitions of healthy and unhealthy snacks (low and high in: kilojoules, fat, salt and sugars, respectively), and examples from each category. Participants then complete measures of snacking behaviour, habit strength (concerning consumption of unhealthy snacks), and intentions to reduce unhealthy snacking. Intention to reduce unhealthy snacking will be measured again, immediately after creating the plan. Participants will be emailed a reminder of their personal plan at baseline (within the first week), and before then end of the 2nd and 3rd weeks to increase compliance and retention. Consistent with our previous study, in which a change in snacking scores was detected as a result of the intervention after 4 weeks (15), participants in this study will also complete a follow-up survey after 4 weeks. In addition, the 4-week period was selected as it is a tangible time period over which participants can recall their behaviour, and the instrument for the primary outcome has been validated for recall over the previous month (20). The follow-up survey consists of the same description of reasons to reduce unhealthy snacking and definition, followed by measures of snacking behaviour, habit strength and intention. Action control will also be measured in the follow-up survey.

Measures

Screening measures

Prior to beginning the survey, participants will be asked to indicate whether they have type 2 diabetes, and to provide their height (cm or feet and inches) and weight (kg).

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Demographic measures

Participants will be asked to complete questions about their age, employment status, highest level of educational attainment, and, if they report having diabetes, years since diagnosis and whether or not they use insulin.

Health literacy

Health literacy will be measured using the Newest Vital Sign (NVS)(23), a 6-item measure of functional health literacy, and a single-item literacy screener (24). NVS scores of 0-1 indicate a high likelihood of limited healthy literacy, scores of 2-3 indicate the possibility of limited health literacy and scores of 4-6 indicate adequate health literacy.

Need for cognition

Need for cognition describes the extent that an individual engages in and enjoys cognitively effortful activities (i.e. activities that require a lot of thinking) (25). Three items on a 7-point likert scale (strongly disagree to strongly agree) will assess the participant's need for cognition (26).

Primary outcome

Snack scores (previous month)

Snacking scores will be measured using a validated 7-item measure based on a diet score developed by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) (20). Items are drawn from the 'discretionary foods' category which the Australian Guidelines to Healthy Eating define as foods 'not considered necessary for a healthy diet'. Alcohol was excluded from the assessment in this study as the focus is on 'snacks.' Participants answer how many serves of unhealthy snacks they ate in the past month. Participants can answer according to the number of serves per day, week or month. Average weekly serves of unhealthy snacks will be calculated from these scores. Although electronic diaries might overcome some limitations of once-off measures of snacking behaviour such as

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that described above, electronic diaries were unavailable at the time of study development due to the budget and technical constraints. This approach chosen also reduces participant burden and minimises the risk of missing data.

Secondary outcomes

Perceived unhealthy/healthy snacking (previous week)

Two items, each on a 7-point Likert scale will assess perceived extent of healthy and unhealthy snacking in the previous week, respectively. Healthy snacks are described to participants as those that are low in kilojoules, fat, salt and sugars. Unhealthy snacks are described as high in kilojoules, fat, salt and sugars. Examples of healthy and unhealthy snacks are provided.

Intention, habit strength and action control

The measure of intention consists of 3 items that ask about the participant's intention to reduce unhealthy snacking (27, 28). Habit strength will be assessed using the 12-item self-report habit strength index (29), and action control will be assessed using a 6-item measure (30). Responses to each item are recorded on 7-point Likert scales (strongly disagree to strongly agree).

Difficulty using the planning tool

A single item will ask participants to rate how hard it was to use the planning tool (1=not at all hard, 5=extremely hard).

Preferred action plan at follow-up

At follow-up, participants will be reminded of the name and logo used for their plan. Participants will be shown an image slider that contains screenshots from the other action plan. Participants will then be asked: "If you were given the choice, which action plan would you prefer to use next time?"

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Sample size

The proposed study will seek to analyse a sample of 2,000 Australian participants at follow-up with high BMI (overweight/obese) and/or type 2 diabetes. At baseline participants will be randomised at a ratio of 2:1:1 to each allocation method arm, such that there are a total of 1,000 participants in the random arm (who will then be evenly randomised to assess or not assess their preference for a particular action plan before they are ultimately randomised to an action plan), and 500 in the two remaining allocation method arms (the screened and choice arms). With a two sided alpha of 0.05 and power of 80%, a sample of this size will allow us to detect a small main effect of $f = 0.08$ in a univariate ANOVA comparing the three allocation method arms and in a univariate ANOVA comparing the two prior-preference assessment arms; this corresponds to a minimum pairwise difference between the two most extreme mean values of approximately 0.18 standard deviations. Estimates of effect size are based on the outcome of previous work exploring the effects of action plans on unhealthy snacking (15).

Based on our previous studies recruiting through this provider, we anticipate an attrition rate no greater than 15% by one month follow-up. Therefore, we estimate a total of 2, 352 should be recruited at baseline to ensure sufficient sample size for analysis.

A sample of this size will also ensure that there is at least 80% power for secondary analysis conducted to estimate treatment and preference effects (20, 31) with a treatment effect between the two interventions (literacy-sensitive and standard planning tools) as small as 0.25 standard deviations (estimated as 5 snacks per month based on previous findings (15)), and a preference effect, comparing those who received their preferred tool to those who did not, as small as 0.35 standard deviations (approximately 7 snacks per month). This assumes that approximately equal proportions of participants will choose the literacy-sensitive and

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standard planning tools in the choice arm, and that there will be approximately equal proportions of participants allocated to each of these interventions in the screened arm.

Piloting

The intervention will be piloted with 200 participants to check that approximately equal numbers of participants allocated to the choice condition select each of the interventions. If required, sample size estimates will be adjusted to ensure that the study is sufficiently powered. Piloting will also allow us to assess participant burden and intervention acceptability.

Analysis:

Follow-up outcome measures for participants who do not complete the follow-up survey will be estimated for worst-case (no change in snacking score) and best-case scenarios (average-change in snack score). These estimates will be incorporated as an intention-to-treat analysis. Baseline characteristics of completers and non-completers will be compared to assess bias and generalisability.

Confirmatory analysis

A confirmatory analysis will replicate the analysis previously reported (15) to examine if the treatment effect is modified by health literacy. Multiple linear regression models including an intervention group × health literacy (NVS score) interaction term will be used to predict follow-up snacking scores and perceived difficulty using the plan. Important correlates of health literacy (age, level of education, language spoken at home) (2), diabetes status and baseline snacking will be controlled for in the model. NVS scores will be examined both continuously and categorically (i.e., inadequate vs. adequate health literacy).

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Assessment of prior preference analysis

For participants in the random arm of the study, participants whose action plan preference was assessed prior to randomisation to an intervention will be compared to those whose preference was not assessed. Multiple linear regression (controlling for health literacy, age, level of education, language spoken at home and baseline snacking) will evaluate the effect of preference assessment on unhealthy snacking behaviour. For participants who provided a preference, an additional multiple linear regression will evaluate the effect of participants receiving their preferred intervention compared to those not receiving their preferred intervention on unhealthy snacking behaviour.

Analysis of effects of allocation method

The primary analysis will use regression to test for a difference in self-reported unhealthy snacking between the three randomised arms (random, screened, and choice) whilst adjusting for any effect of diabetes status. An adjusted model will also be constructed to allow for any baseline imbalances in the potential confounders including age, English as a second language, level of education. The analysis will be repeated on the secondary outcomes of perceived unhealthy snacking in the previous week, snacks consumed the previous day, difficulty using the planning tool, action control, and habit strength with similar adjustment for diabetes status and any baseline imbalances. A sub-analysis will also be conducted on participants with and without type 2 diabetes.

An appropriate analysis that uses the available preference information will be used to estimate treatment, preference and selection effects for the primary outcome (32). The treatment effect compares the efficacy of the health literate action plan with the standard action plan in the random arm. The preference effect and selection effects are estimated using the random and choice arms. The preference effect measures the difference in self-reported

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unhealthy snacking for those who received their preferred action plan compared to those who did not receive their preferred action plan. The selection effect measures the difference between those who would select the literacy-sensitive intervention with those who would select the standard intervention regardless of which intervention they received. Secondary analyses will adjust for diabetes status, and baseline imbalances in potential confounders including age, English as a second language, level of education. Data from participants in the screened arm will also be analysed in this manner, producing estimates analogous to the preference and selection effects.

These effects will also be estimated for the secondary outcomes of perceived unhealthy snacking in the previous week, snacks consumed the previous day, difficulty using the planning tool, action control, and habit strength with similar adjustment for diabetes status and any baseline imbalances.

Bootstrapping, by taking repeated random samples with replacement, will be used to estimate the difference between the preference effect (estimated using choice arm) and an analogous effect estimated using the screened arm, as well as the difference between the selection effect (estimated using the choice arm) and an analogous effect estimated using the screened arm. Bootstrapping will also be used to estimate the confidence intervals for non-continuous outcome measures. The bootstrapping is necessary, as the variances for the estimated differences and non-continuous outcomes have not been derived previously (33).

Additional analysis

Two researchers will also independently code standard action plans to indicate the extent that participants followed standard action plan instructions (that is, provided at least one 'situation', and one 'plan') and the extent that plans differed from the pre-determined options presented in the literacy-sensitive action plans (for example, situations or solutions that did

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not correspond to options listed in the literacy-sensitive action plan, or strategies that fell outside of the "If-then" construction. The latter may include, for example, making sure healthy snacks are prepared in advance, or refraining from buying certain foods at the supermarket). Coders will be blind to the health literacy level of participants. Any disagreements will be systematically resolved through discussion. Results from this content analysis will also inform a secondary analysis of the impact of allocation method and action plan on snacking scores.

Data management

De-identified data will be captured electronically on the secure Qualtrics server. Data will be stored securely in de-identified form, with a unique participant ID to link responses from the baseline and follow-up surveys. In all forms of dissemination, only de-identified data will be presented as group means and differences to maintain the anonymity of participants. In line with National Health and Medical Research Council (NHMRC) recommendations, and University of Sydney policies, all data will be kept for a minimum 5 years.

Ethics and dissemination

This study was approved by the University of Sydney Human Research Ethics Committee [2017/793]. The interventions used in this study are practical; they can be easily incorporated into existing self-management practices, particularly with the use of online technologies, and are low in cost. Ascertaining an effective way to tailor planning tools to health literacy level (that is, allowing the participant to choose by employing a screening tool) will provide valuable information for implementation in apps that target people with varying health literacy levels. Findings from this study will be disseminated through peer-reviewed publication and national and international conference presentations. Findings will also be

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disseminated through community and research partnerships with groups such as Western Sydney Diabetes.

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Authors' contributions

Conceptualisation, methodology, writing – review and editing: JA, CB, EC, RT, SW, KM

Investigation, project administration: JA

Writing – original draft preparation: JA, EC, RT

Software: RT

Supervision: EC, CB, KM

Funding acquisition: CB, JA, RT, KM

Data availability statement

There are no data in this work. No data are as yet available for this study as recruitment is currently under way.

Funding statement

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Competing interests statement

Authors have no competing interests.

Acknowledgements

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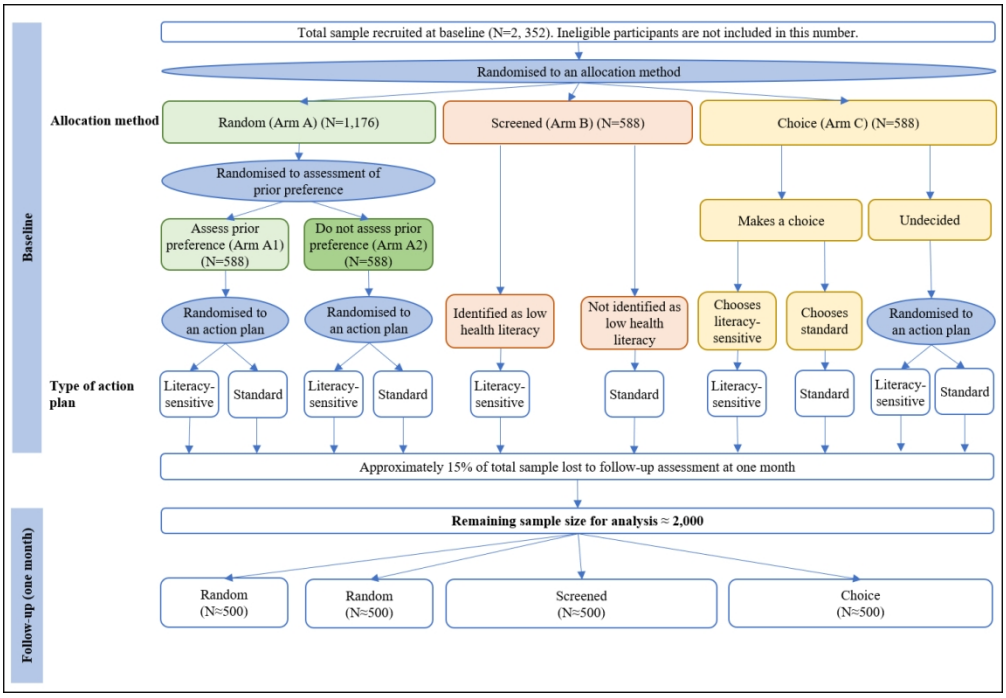

Figure 1: Anticipated participant recruitment and attrition to achieve sufficient sample size

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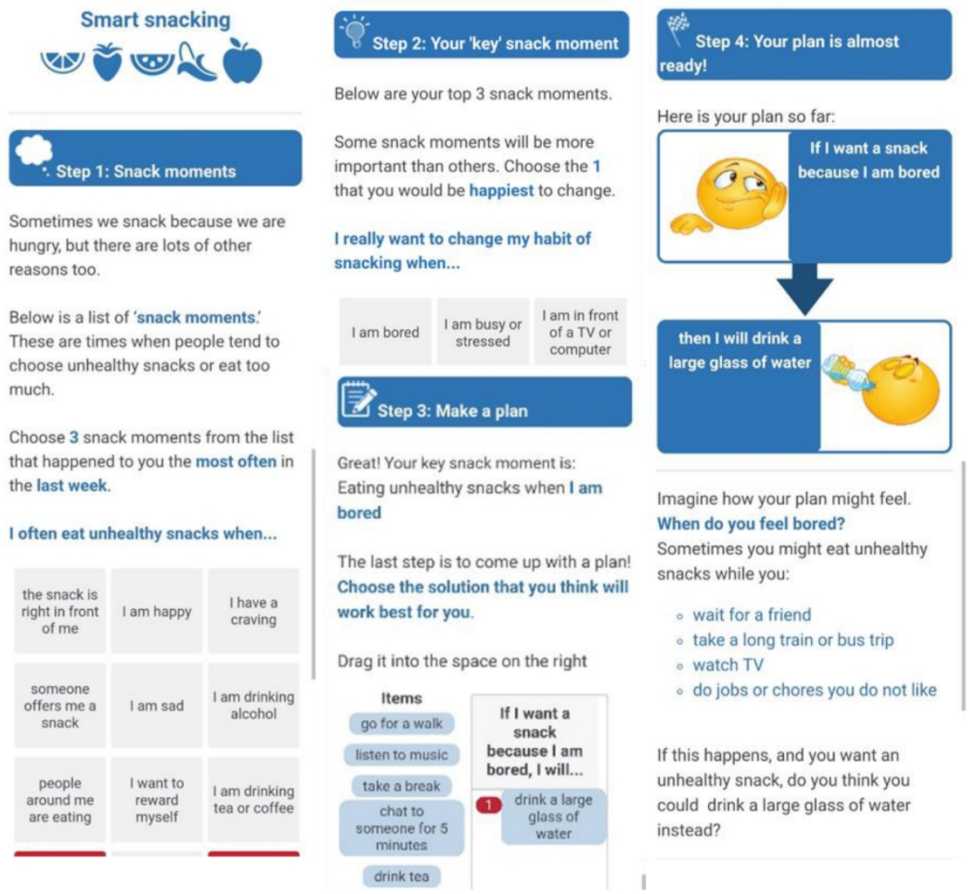

Figure 2: Mobile screenshots from literacy-sensitive action plan. From left to right: a) Step 1: Selecting top 3 snacking scenarios; b) Step 2: Selecting 1 key scenario; c) Step 3: Selecting a solution; d) Step 4: Imagining the plan

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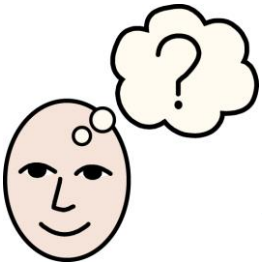
THE UNIVERSITY OF SYDNEY

Study Information Sheet:
Smart snacking: An online planning tool



What is the study about?

We are doing a research study to find out more about tools to help people eat less unhealthy snacks. While many of us want to change the way we snack, this can be very hard. Often we make plans but have trouble sticking to them over long periods of time. This study will look at online tools that help people stick to their plans.

Who is carrying out the study?

We are from the School of Public Health at the University of Sydney. Our names are:

- Julie Ayre
- Carissa Bonner
- Robin Turner
- Erin Cvejic
- Kirsten McCaffery
- Stephen Walter

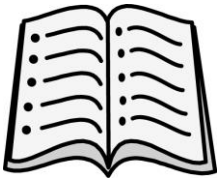
What will happen if I say that I want to be in the study?

You can decide if you want to take part in the study or not. Please read this sheet carefully so that you can make up your mind about whether you want to take part. Completing a question in the online survey is an indication of your consent to take part in the study.

You may stop completing the online survey at any point if you do not wish to continue, and we will not use your answers. You do not have to give a reason for not taking part. Once you have submitted your survey anonymously, your responses cannot be withdrawn.

If you decide that you want to be in our study, we will ask you to:

1. Complete questions online (for example, about the foods you eat and snacking habits)
2. Use the online planning tool to create a plan to help you eat less unhealthy snacks. We will ask you to follow the plan for 4 weeks. You will receive 3 reminder messages about your plan during that time.
3. Complete questions online about your snacking behaviour and your plan after 4 weeks.



Will anyone else know what I say in the study?

All of the information that we have about you from the study will be confidential. It will be stored in a safe place at the University of Sydney.

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We will write a report about the study and show it to other people but no one will know that you were in the study.

How long will the study take?

- The **first part** of the study will take about **20 minutes**.
- You will be asked to **try out your snacking plan** for **4 weeks**.
- The **second part** of the study (after 4 weeks) will take about **10 minutes**.

Are there any good things about being in the study?

This study may help you think more about the way that you snack. This is the first step to changing your eating patterns.

Are there any bad things about being in the study?

This study will take up some of your time, but we don't think it will be bad for you or cost you anything.

By giving your consent to take part in this study you are telling us that you:

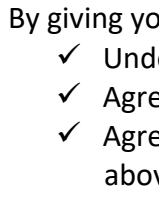
- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as described above.
- ✓ Agree to the use of your personal information for the research purposes described above.

What if I want more information about the study or my involvement in it?

You can contact the researcher Julie Ayre:

- **Call:** (02) 9351 7789
- **Email:** julie.ayre@sydney.edu.au.

What if I am not happy with the study or the people doing the study?



The ethical aspects of this study have been approved by the HREC of the University of Sydney [Project Number 2018/793].

If you are not happy with how we are doing the study or how we treat you, then you can:

- **Call** the university on +61 2 8627 8176 or
- Write an **email** to human.ethics@sydney.edu.au

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Supplementary Material: Behaviour Change Techniques present in intervention

Supplementary Table 1: Behaviour Change Techniques present in intervention

Intervention	Intervention feature	Behaviour change technique
Literacy-sensitive	The text 'forming plans has shown to improve snacking habits'	Credible source
	Identifying situations for unhealthy snacking	Problem solving
	Identifying an alternative behaviour to enact in snacking situation	Behaviour substitution
	Generation of plan (with images) to reduce unhealthy snacking	Action planning
	Instruction to imagine enacting the plan	Mental rehearsal of a successful performance
	Reminder emails	Prompts/cues
Standard	The text 'forming plans has shown to improve snacking habits'	Credible source
	Identifying situations for unhealthy snacking	Problem solving
	Generation of plan to reduce unhealthy snacking	Action planning
	Reminder emails	Prompts/cues

Note: **Behaviour Change Techniques are based on the Behaviour Change Technique Taxonomy v1 (Michie et al., 2013)**

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

Section / Item	Item Number	Description	
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	3 (available from ANZCTR)
Protocol version	3	Date and version identifier	3 (As shown in ANZCTR)
Funding	4	Sources and types of financial, material, and other support	24
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Role 24
	5b	Name and contact information for the trial sponsor	1
	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	24
	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)	N/A
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	4-6
	6b	Explanation for choice of comparators	4-5

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Objectives	7	Specific objectives or hypotheses	5-6
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)	6

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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	6-7
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)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-12
	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)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	12 (reminders emails)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
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	13-14
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)	8 (fig 1); 12
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	14-15
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	6-7; 14-15

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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	7
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	7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	18
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
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	12-14
	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	12 (reminders emails)
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	18-19

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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	16-18
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16-18
	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)	16
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	N/A
	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	15
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	Supp (PIS)
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research and ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
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)	N/A as not anticipated; however protocol updates can be as per trial

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			registry pg 3
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6-7, Supp PIS
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	18-19
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
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	19
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant level dataset, and statistical code	3, 18-19
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supp PIS
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

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*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.

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