CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and Internet-based applications/interventions, including mobile interventions, electronic games (incl multiplayer games), social media, certain telehealth applications, and other interactive and/or networked electronic applications. Some of the items (e.g. all subitems under item 5 - description of the intervention) may also be applicable for other study designs.

The goal of the CONSORT EHEALTH checklist and guideline is to be
a) a guide for reporting for authors of RCTs,
b) to form a basis for appraisal of an ehealth trial (in terms of validity)

CONSORT-EHEALTH items/subitems are MANDATORY reporting items for studies published in the Journal of Medical Internet Research and other journals / scientific societies endorsing the checklist.

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (non-pharmacologic treatment) items.
Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

As the CONSORT-EHEALTH checklist is still considered in a formative stage, we would ask that you also RATE ON A SCALE OF 1-5 how important/useful you feel each item is FOR THE PURPOSE OF THE CHECKLIST and reporting guideline (optional).

Mandatory reporting items are marked with a red *.
In the textboxes, either copy & paste the relevant sections from your manuscript into this form - please include any quotes from your manuscript in QUOTATION MARKS, or answer directly by providing additional information not in the manuscript, or elaborating on why the item was not relevant for this study.

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED).

Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

DO NOT FORGET TO SAVE AS PDF _AND_ CLICK THE SUBMIT BUTTON SO YOUR ANSWERS ARE IN OUR DATABASE !!!

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption):
Eysenbach G, CONSORT-EHEALTH Group
CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions
J Med Internet Res 2011;13(4):e126
URL: http://www.jmir.org/2011/4/e126/
doi: 10.2196/jmir.1923
PMID: 22209829

kiera.bartlett.uom@gmail.com (not shared) Switch account

Draft saved

* Required

Your name *
First Last

Yvonne Kiera Bartlett

Primary Affiliation (short), City, Country *
University of Toronto, Toronto, Canada

University of Manchester

Your e-mail address *
abc@gmail.com

kiera.bartlett@manchester.ac.uk

Title of your manuscript *
Provide the (draft) title of your manuscript.

Effects of Using a Text Message Intervention on Psychological Constructs and the Association Between Changes to Psychological Constructs and Medication Adherence in People With Type 2 Diabetes: Results From a Randomized Controlled Feasibility Study
Name of your App/Software/Intervention *
If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

SuMMiT-D (Support through Mobile Messaging)

Evaluated Version (if any)
e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

N/A not multiple versions

Language(s) *
What language is the intervention/app in? If multiple languages are available, separate by comma (e.g. "English, French")

English

URL of your Intervention Website or App
e.g. a direct link to the mobile app on app in appstore (itunes, Google Play), or URL of the website. If the intervention is a DVD or hardware, you can also link to an Amazon page.

https://www.phc.ox.ac.uk/research/participate/summit-d (This is the study website. The inte

URL of an image/screenshot (optional)

Your answer
Accessibility *
Can an enduser access the intervention presently?

- access is free and open
- access only for special usergroups, not open
- access is open to everyone, but requires payment/subscription/in-app purchases
- app/intervention no longer accessible
- Other:

Primary Medical Indication/Disease/Condition *
e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)"

Type 2 Diabetes

Primary Outcomes measured in trial *
comma-separated list of primary outcomes reported in the trial

Feasibility of recruitment, randomisation, ques

Secondary/other outcomes
Are there any other outcomes the intervention is expected to affect?

Your answer
Recommended "Dose" *
What do the instructions for users say on how often the app should be used?

- Approximately Daily
- Approximately Weekly
- Approximately Monthly
- Approximately Yearly
- "as needed"
- Other: This intervention is not an app. Messages are sent several times a week.

Approx. Percentage of Users (starters) still using the app as recommended after 3 months *

- unknown / not evaluated
- 0-10%
- 11-20%
- 21-30%
- 31-40%
- 41-50%
- 51-60%
- 61-70%
- 71%-80%
- 81-90%
- 91-100%
- Other: The intervention is not an app.
Overall, was the app/intervention effective? *

- yes: all primary outcomes were significantly better in intervention group vs control
- partly: SOME primary outcomes were significantly better in intervention group vs control
- no statistically significant difference between control and intervention
- potentially harmful: control was significantly better than intervention in one or more outcomes
- inconclusive: more research is needed
- Other: **This is a feasibility trial**

Article Preparation Status/Stage *
At which stage in your article preparation are you currently (at the time you fill in this form)

- not submitted yet - in early draft status
- not submitted yet - in late draft status, just before submission
- submitted to a journal but not reviewed yet
- submitted to a journal and after receiving initial reviewer comments
- submitted to a journal and accepted, but not published yet
- published
- Other:
Journal *
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")

- not submitted yet / unclear where I will submit this
- Journal of Medical Internet Research (JMIR)
- JMIR mHealth and UHealth
- JMIR Serious Games
- JMIR Mental Health
- JMIR Public Health
- JMIR Formative Research
- Other JMIR sister journal
- Other:

Is this a full powered effectiveness trial or a pilot/feasibility trial? *

- Pilot/feasibility
- Fully powered

Manuscript tracking number *
If this is a JMIR submission, please provide the manuscript tracking number under "other" (The ms tracking number can be found in the submission acknowledgement email, or when you login as author in JMIR. If the paper is already published in JMIR, then the ms tracking number is the four-digit number at the end of the DOI, to be found at the bottom of each published article in JMIR)

- no ms number (yet) / not (yet) submitted to / published in JMIR
- Other: 30058

TITLE AND ABSTRACT
1a) TITLE: Identification as a randomized trial in the title

1a) Does your paper address CONSORT item 1a? *

I.e does the title contain the phrase “Randomized Controlled Trial”? (if not, explain the reason under "other")

- yes
- Other: It is a randomized controlled feasibility study

1a-i) Identify the mode of delivery in the title

Identify the mode of delivery. Preferably use "web-based" and/or "mobile" and/or "electronic game" in the title. Avoid ambiguous terms like "online", "virtual", "interactive". Use "Internet-based" only if Intervention includes non-web-based Internet components (e.g. email), use "computer-based" or "electronic" only if offline products are used. Use "virtual" only in the context of "virtual reality" (3-D worlds). Use "online" only in the context of "online support groups". Complement or substitute product names with broader terms for the class of products (such as "mobile" or "smart phone" instead of "iphone"), especially if the application runs on different platforms.

1 2 3 4 5
subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 1a-i? *

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Effects of Using a Text Message Intervention"
1a-ii) Non-web-based components or important co-interventions in title
Mention non-web-based components or important co-interventions in title, if any (e.g., "with telephone support").

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| subitem not at all important | | | | | essential |

Does your paper address subitem 1a-ii?
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The intervention is wholly text message-based and identified as such in the title. There are no 'web-based' components.

1a-iii) Primary condition or target group in the title
Mention primary condition or target group in the title, if any (e.g., "for children with Type I Diabetes")
Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| subitem not at all important | | | | | essential |

Does your paper address subitem 1a-iii? *
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Adherence in People With Type 2 Diabetes"
1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions
NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

1b-i) Key features/functionality/components of the intervention and comparator in the METHODS section of the ABSTRACT
Mention key features/functionality/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

1 2 3 4 5

subitem not at all important ○ ○ ○ ● ○ essential

Clear selection

Does your paper address subitem 1b-i? *
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"randomized to either receive a text message–based intervention or care as usual"

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT
Clarify the level of human involvement in the abstract, e.g., use phrases like “fully automated” vs. “therapist/nurse/care provider/physician-assisted” (mention number and expertise of providers involved, if any). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

1 2 3 4 5

subitem not at all important ○ ○ ○ ● ○ essential

Clear selection
Does your paper address subitem 1b-ii?  
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

"text message–only intervention" in the conclusion of the abstract.

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1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT

Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic or a closed online user group (closed usergroup trial), and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment). Clearly say if outcomes were self-assessed through questionnaires (as common in web-based trials). Note: In traditional offline trials, an open trial (open-label trial) is a type of clinical trial in which both the researchers and participants know which treatment is being administered. To avoid confusion, use "blinded" or "unblinded" to indicated the level of blinding instead of "open", as "open" in web-based trials usually refers to "open access" (i.e. participants can self-enrol). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it.)

1-5  
subitem not at all important  
1  2  3  4  5 essential

Does your paper address subitem 1b-iii?  
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

"Adults prescribed oral medication for type 2 diabetes (N=209) were recruited from general practice" is specified in the methods section of the abstract and "self-reported medication adherence" is specified in the objective section of the abstract.
1b-iv) RESULTS section in abstract must contain use data
Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

1 2 3 4 5
subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 1b-iv?
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Number of logins etc. is not relevant in this case as it is a text message intervention. The number of participants enrolled is stated in the methods section of the abstract.

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials
Conclusions/Discussions in abstract for negative trials: Discuss the primary outcome - if the trial is negative (primary outcome not changed), and the intervention was not used, discuss whether negative results are attributable to lack of uptake and discuss reasons. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

1 2 3 4 5
subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 1b-v?
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

N/A not a negative trial

⚠️ Your answer must have a minimum of 25 characters.
INTRODUCTION

2a) In INTRODUCTION: Scientific background and explanation of rationale

2a-i) Problem and the type of system/solution
Describe the problem and the type of system/solution that is object of the study: intended as stand-alone intervention vs. incorporated in broader health care program? Intended for a particular patient population? Goals of the intervention, e.g., being more cost-effective to other interventions, replace or complement other solutions? (Note: Details about the intervention are provided in "Methods" under 5)

1 2 3 4 5
subitem not at all important ○ ○ ○ ● ○ essential

Clear selection

Does your paper address subitem 2a-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Describe the problem: "Poor adherence to oral treatments is common in people with type 2 diabetes [1,2]. When such medication is taken suboptimally, blood glucose control can be poorer, leading to greater risk of developing complications [3]."
Proposed solution: "A library of text messages was developed to deliver specified BCTs that target multiple constructs relevant to this model (see Table 1). The included constructs relate to both intentional and nonintentional nonadherence."
2a-ii) Scientific background, rationale: What is known about the (type of) system

Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropriate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.

Does your paper address subitem 2a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Our previous research has confirmed that the messages in the library are good examples of the BCTs they were written to represent and are acceptable to the target population [21]. We are therefore confident that the messages can deliver the intended BCTs; however, at present we do not know if these BCTs will have the proposed effects on psychological constructs or if changes to these psychological constructs will be related to changes in medication adherence. Hence, there was a need for this formative study to indicate if changes are required to the intervention before causal links are further explored in an efficacy trial powered to conduct this analysis."

2b) In INTRODUCTION: Specific objectives or hypotheses

Does your paper address CONSORT subitem 2b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"to answer the following 2 research questions: (1) Does a BCT-based brief message intervention produce changes in psychological constructs relative to control group?; (2) Are changes in psychological constructs correlated with changes in medication adherence?"
METHODS

3a) Description of trial design (such as parallel, factorial) including allocation ratio

Does your paper address CONSORT subitem 3a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"6-month, parallel-group, randomized controlled feasibility trial as part of the Support Through Mobile Messaging and Digital Health Technology for Diabetes (SuMMiT-D) program of work. Participants were randomized in a 1:1 ratio to the intervention or control arm."

3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons

Does your paper address CONSORT subitem 3b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

N/A no changes made following trial commencement
3b-i) Bug fixes, Downtimes, Content Changes

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other "unexpected events” that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].

Does your paper address subitem 3b-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

The text message system was robust throughout.

4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

"Eligible patients were those who were ≥35 years of age, able to use a mobile phone to send and receive text messages, and taking oral medication for type 2 diabetes (including lipid and blood pressure–lowering medications for diabetes). Patients taking oral medication either with or without concomitant insulin were eligible. Patients who had been admitted to hospital in the previous 3 months with hypo- or hyperglycemia, were pregnant, were within 3 months postpartum, were planning a pregnancy within the trial, or had a serious medical condition that, in the opinion of the investigator, made them unable to take part were ineligible."
4a-i) Computer / Internet literacy
Computer / Internet literacy is often an implicit "de facto" eligibility criterion - this should be explicitly clarified.

1 2 3 4 5
subitem not at all important ○ ○ ● ○ ○ essential

Does your paper address subitem 4a-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

"able to use a mobile phone to send and receive text messages" is defined in the eligibility criteria.

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:
Open vs. closed, web-based vs. face-to-face assessments: Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic, and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. In online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these.

1 2 3 4 5
subitem not at all important ○ ○ ● ○ ○ essential
Does your paper address subitem 4a-ii? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks *like this* to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

*The allocated intervention was then delivered directly through an online platform. Aside from those conducting qualitative interviews and the engineering team, all other research team members and health care staff were blinded. *

*Assessments were completed online or on paper.*

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4a-iii) Information giving during recruitment

Information given during recruitment. Specify how participants were briefed for recruitment and in the informed consent procedures (e.g., publish the informed consent documentation as appendix, see also item X26), as this information may have an effect on user self-selection, user expectation and may also bias results.

Does your paper address subitem 4a-iii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks *like this* to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

*Potentially eligible patients were contacted about the study by the practice and invited to send a text message to express interest. On receipt of the text message, further information about the study was given either online or by post, and eligibility was assessed by the researchers by phone.*

*Informed consent was given either online or by post.*

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4b) Settings and locations where the data were collected
Does your paper address CONSORT subitem 4b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Participants were recruited from 16 general practices in England between January 2019 and June 2019."

4b-i) Report if outcomes were (self-)assessed through online questionnaires
Clearly report if outcomes were (self-)assessed through online questionnaires (as common in web-based trials) or otherwise.

1 2 3 4 5
subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 4b-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"At baseline, participants completed a demographic questionnaire and provided their postcode, and at baseline and 6 months, participants completed the 5-item Medication Adherence Report Scale (MARS) [23,24] and a health psychology questionnaire."

4b-ii) Report how institutional affiliations are displayed
Report how institutional affiliations are displayed to potential participants [on ehealth media], as affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention. (Not a required item – describe only if this may bias results)

1 2 3 4 5
subitem not at all important ○ ○ ○ ○ ○ essential

Clear selection
Does your paper address subitem 4b-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Intervention is text-message based

5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a “Conflict of interest” section or mentioned elsewhere in the manuscript).

1 2 3 4 5
subitem not at all important ○ ○ ● ○ ○ essential

Clear selection

Does your paper address subitem 5-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

University of Manchester and University of Oxford logos used and mentioned in the text of recruitment materials and participant information sheets.
5-ii) Describe the history/development process

Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results.

1 2 3 4 5
subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Clear selection

Does your paper address subitem 5-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Previous development paper referenced: "Our previous research has confirmed that the messages in the library are good examples of the BCTs they were written to represent and are acceptable to the target population [21]."

5-iii) Revisions and updating

Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was “frozen” during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b).

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subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Clear selection

Does your paper address subitem 5-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

No updates needed during the feasibility trial
5-iv) Quality assurance methods

Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.

1  2  3  4  5

subitem not at all important 1 1 3 0 0 essential

Clear selection

Does your paper address subitem 5-iv?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The text messages were reviewed multiple times by different stakeholders during development. Further information available in [21].

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used. Replicability (i.e., other researchers should in principle be able to replicate the study) is a hallmark of scientific reporting.

1  2  3  4  5

subitem not at all important 1 1 3 0 0 essential

Clear selection

Does your paper address subitem 5-v?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The text message library is currently being used in a trial so is not available publicly as yet.
5-vi) Digital preservation
Digital preservation: Provide the URL of the application, but as the intervention is likely to change or disappear over the course of the years; also make sure the intervention is archived (Internet Archive, webcitation.org, and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

1 2 3 4 5
subitem not at all important 0 0 ☀ 0 0 essential

Clear selection

Does your paper address subitem 5-vi?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not relevant for a text message intervention

5-vii) Access
Access: Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group. If known, describe how participants obtained “access to the platform and Internet” [1]. To ensure access for editors/reviewers/readers, consider to provide a “backdoor” login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi).

1 2 3 4 5
subitem not at all important 0 0 ☀ 0 0 essential

Clear selection
Does your paper address subitem 5-vii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Potentially eligible patients were contacted about the study by the practice and invited to send a text message to express interest."

"Participants in the intervention group were sent up to 4 text messages per week for 6 months."

5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc., see e.g., [7, 8] for terminology). This includes an in-depth description of the content (including where it is coming from and who developed it) [1], whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback" [6]. This also includes a description of communication delivery channels and – if computer-mediated communication is a component – whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].

Clear selection
"There were 2 categories of messages: (1) those targeting medication adherence based on BCTs identified as relevant for this population [15] that have previously been confirmed as representing the intended BCT and being acceptable to the target population [21] and (2) those targeting diet and physical activity, introduced as a response to feedback during the development process, indicating that a broader view of diabetes self-management may benefit engagement. Messages in category 2 provided information from and links to credible sources such as the Diabetes UK or NHS Choices website. All messages were sent at a preferred time (AM or PM), and participants were able to text back "like" or "dislike" after any message received. For messages targeting medication adherence, texting "like" doubled the chance a future message would come from the same BCT as the message that had been liked, while texting "dislike" halved the chance of a future message coming from the same BCT as the disliked message. Texting "like" or "dislike" following messages targeting diet or physical activity did not result in any change."

In addition the specific BCTs used and the logic model are provided.

"Participants in the intervention group were sent up to 4 text messages per week for 6 months."
5-x) Clarify the level of human involvement

Clarify the level of human involvement (care providers or health professionals, also technical assistance) in the e-intervention or as co-intervention (detail number and expertise of professionals involved, if any, as well as "type of assistance offered, the timing and frequency of the support, how it is initiated, and the medium by which the assistance is delivered". It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

1 2 3 4 5
subitem not at all important ○ ○ ● ○ ○ essential

Clear selection

Does your paper address subitem 5-x?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Throughout the intervention is described as a 'text message only intervention'

5-xi) Report any prompts/reminders used

Report any prompts/reminders used: Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency etc. It may be necessary to distinguish between the level of prompts/reminders required for the trial, and the level of prompts/reminders for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

1 2 3 4 5
subitem not at all important ○ ○ ○ ● ○ essential

Clear selection
Does your paper address subitem 5-xi? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This information is provided in the protocol paper [22]

5-xii) Describe any co-interventions (incl. training/support)
Describe any co-interventions (incl. training/support): Clearly state any interventions that are provided in addition to the targeted eHealth intervention, as eHealth intervention may not be designed as stand-alone intervention. This includes training sessions and support [1]. It may be necessary to distinguish between the level of training required for the trial, and the level of training for a routine application outside of a RCT setting (discuss under item 21 – generalizability.

1 2 3 4 5
subitem not at all important 〇 〇 〇 〇 essential

Does your paper address subitem 5-xii? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No co-interventions provided

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
Does your paper address CONSORT subitem 6a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Assessments were completed online or on paper. At baseline, participants completed a demographic questionnaire and provided their postcode, and at baseline and 6 months, participants completed the 5-item Medication Adherence Report Scale (MARS) [23,24] and a health psychology questionnaire. The 5 items on the MARS are nonadherent behaviors, and thus participants respond by indicating how true each statement is for them on a 5-point scale from “always true” to “never true.” One item referred to nonintentional nonadherence, “I forget to take my diabetes medicines,” while the other 4 items measured intentional nonadherence.

The hypothesized mechanisms of action questionnaire was developed for this study and measured key constructs targeted by the messages (see Table 2). Two items were used to measure each of the following fourteen constructs: action self-efficacy, necessity, concerns, intention, automaticity, maintenance self-efficacy, recovery self-efficacy, action planning, coping planning, action control, prompts and cues, social support, satisfaction with the experienced consequences of behavior, and risk perception. The 28 items were sourced or adapted from previously developed questionnaires where possible and were phrased to specifically relate to taking diabetes tablets as prescribed (see Table 2). All questions were answered using a 5-point Likert scale with the anchors strongly disagree, disagree, neither agree nor disagree, agree, and strongly agree. For further details on additional measures taken but not reported here, see Farmer et al [22]."

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

If outcomes were obtained through online questionnaires, describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed [9].

1 2 3 4 5

subitem not at all important ● ● ● ● ● essential

Clear selection
Does your paper address subitem 6a-i?
Copy and paste relevant sections from manuscript text

Your answer

6a-ii) Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored
Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored (logins, logfile analysis, etc.). Use/adoptions metrics are important process outcomes that should be reported in any e-health trial.

1 2 3 4 5
subitem not at all important   essential
Clear selection

Does your paper address subitem 6a-ii?
Copy and paste relevant sections from manuscript text

This is a text message intervention, ‘use’ involves receiving text messages.

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained
Describe whether, how, and when qualitative feedback from participants was obtained (e.g., through emails, feedback forms, interviews, focus groups).

1 2 3 4 5
subitem not at all important   essential
Clear selection
Does your paper address subitem 6a-iii?
Copy and paste relevant sections from manuscript text

Qualitative results are not reported in this paper.

6b) Any changes to trial outcomes after the trial commenced, with reasons

Does your paper address CONSORT subitem 6b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No changes made

⚠️ Your answer must have a minimum of 25 characters.

7a) How sample size was determined
NPT: When applicable, details of whether and how the clustering by care provides or centers was addressed

7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size
Describe whether and how expected attrition was taken into account when calculating the sample size.

| Subitem not at all important | 1 | 2 | 3 | 4 | 5 |
|------------------------------|---|---|---|---|---|
| Total                        |   |   |   |   |   |

Clear selection
7b) When applicable, explanation of any interim analyses and stopping guidelines

Does your paper address CONSORT subitem 7b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

N/A no interim analysis

Your answer must have a minimum of 25 characters.

8a) Method used to generate the random allocation sequence

NPT: When applicable, how care providers were allocated to each trial group

Does your paper address CONSORT subitem 8a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Randomization was completed through a validated secure web-based program (Sortition) using a nondeterministic minimization algorithm to ensure groups were balanced for age, study site, gender, duration of diabetes, and number of medications."

8b) Type of randomisation; details of any restriction (such as blocking and block size)
9) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

Does your paper address CONSORT subitem 9? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Randomization was completed through a validated secure web-based program (Sortition) using a nondeterministic minimization algorithm to ensure groups were balanced for age, study site, gender, duration of diabetes, and number of medications."

10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Does your paper address CONSORT subitem 10? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Randomization was completed through a validated secure web-based program (Sortition) using a nondeterministic minimization algorithm to ensure groups were balanced for age, study site, gender, duration of diabetes, and number of medications."

"Aside from those conducting qualitative interviews and the engineering team, all other research team members and health care staff were blinded."
11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

NPT: Whether or not administering co-interventions were blinded to group assignment

11a-i) Specify who was blinded, and who wasn’t

Specify who was blinded, and who wasn’t. Usually, in web-based trials it is not possible to blind the participants [1, 3] (this should be clearly acknowledged), but it may be possible to blind outcome assessors, those doing data analysis or those administering co-interventions (if any).

1 2 3 4 5
subitem not at all important ○ ○ ○ □ ○ essential

Does your paper address subitem 11a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Aside from those conducting qualitative interviews and the engineering team, all other research team members and health care staff were blinded."

11a-ii) Discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”

Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator".

1 2 3 4 5
subitem not at all important ○ ○ □ ○ ○ essential

Clear selection
Does your paper address subitem 11a-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Participants in the intervention group were sent up to 4 text messages per week for 6 months."

"Participants in the control group received 1 message per month for 6 months thanking them for their participation in the study; this was in addition to their usual care."

11b) If relevant, description of the similarity of interventions
(this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)

Does your paper address CONSORT subitem 11b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Intervention and control arm fully described

12a) Statistical methods used to compare groups for primary and secondary outcomes
NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed
Does your paper address CONSORT subitem 12a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

*The index of multiple deprivation (IMD) is a measure of relative deprivation used by the English government. Areas (32,844 across England) are ranked according to a variety of domains, including income, employment, health, and crime, and then the ranked list is divided into deciles [32]. Participants’ postcodes were used to identify their IMD decile (1 missing, postcode invalid). Descriptive statistics were used to describe age, gender, and IMD, while a t test or chi-squared test was used to assess differences in these variables between those who did and did not complete follow-up assessments. Responses were coded in the following fashion according to the MARS: never true=5, rarely true=4, sometimes true=3, often true =2, and always true=1. Thus, higher scores would be associated with better self-reported adherence. The hypothesized mechanisms of action questionnaire was scored as follows: strongly agree=5, agree=4, neither agree nor disagree=3, disagree=2, and strongly disagree=1. Thus, higher scores would be associated with higher levels of the construct (eg, greater action control, higher self-efficacy, or higher concerns). Construct scores were calculated by summing the scores for both items. Interitem correlations were calculated (see Table 2).

Research Question 1: Does a BCT-Based Brief Message Intervention Produce Changes in Psychological Constructs Relative to a Control Group?
Repeated-measures analysis of covariance (ANCOVA) was conducted for each construct, with time as a within-subject factor at 2 levels (baseline and 6-month follow-up); group (intervention or control) as a between-subject factor; and age, gender, and IMD included as covariates. As a sensitivity analysis, univariate ANCOVA for each construct were conducted, with construct at follow-up as the dependent variable; gender and experimental group as fixed factors; and construct at baseline, age, and IMD as covariates.

Research Question 2: Are Changes in Psychological Constructs Correlated With Changes in Medication Adherence?
Standardized residual change scores were calculated using linear regression for each construct (baseline to follow-up) and MARS (baseline to follow-up). Spearman rho correlation coefficients were then calculated to assess the relationship between change in standardized residuals for each construct and change in self-reported adherence."
12a-i) Imputation techniques to deal with attrition / missing values

Imputation techniques to deal with attrition / missing values: Not all participants will use the intervention/comparator as intended and attrition is typically high in ehealth trials. Specify how participants who did not use the application or dropped out from the trial were treated in the statistical analysis (a complete case analysis is strongly discouraged, and simple imputation techniques such as LOCF may also be problematic [4]).

1 2 3 4 5

- subitem not at all important
- essential

Does your paper address subitem 12a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

All participants who provided data were analysed. No imputation methods were used for people who did not complete measures.

12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses

Does your paper address CONSORT subitem 12b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

*Sensitivity analysis treating baseline variables as covariates rather than as within-subject factors showed aligned significant or nonsignificant effects for 12 of the 14 constructs measured. Previously significant effects on recovery self-efficacy (P=.12) and maintenance self-efficacy (P=.30) were not replicated.*

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under “Methods”] (not a CONSORT item)
X26-i) Comment on ethics committee approval

Does your paper address subitem X26-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Ethical Approval
Ethical approval for the study was granted by National Health Service (NHS) West of Scotland Research Ethics Committee 05. The trial is registered in the ISRCTN registry (ISRCTN13404264).

Ref:18/WS/0173

x26-ii) Outline informed consent procedures
Outline informed consent procedures e.g., if consent was obtained offline or online (how? Checkbox, etc.?), and what information was provided (see 4a-ii). See [6] for some items to be included in informed consent documents.

Ethical Approval
Ethical approval for the study was granted by National Health Service (NHS) West of Scotland Research Ethics Committee 05. The trial is registered in the ISRCTN registry (ISRCTN13404264).

Ref:18/WS/0173
RESULTS

13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center
Does your paper address CONSORT subitem 13a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Yes, this information is provided in the CONSORT diagram in Figure 2.

13b) For each group, losses and exclusions after randomisation, together with reasons

Does your paper address CONSORT subitem 13b? (NOTE: Preferably, this is shown in a CONSORT flow diagram) *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Yes, this information is provided in the CONSORT diagram in Figure 2.

13b-i) Attrition diagram

Strongly recommended: An attrition diagram (e.g., proportion of participants still logging in or using the intervention/comparator in each group plotted over time, similar to a survival curve) or other figures or tables demonstrating usage/dose/engagement.

Subitem not at all important: 1, 2, 3, 4, 5

Participants received the messages for 6 months, they could not continue after this time.

Does your paper address subitem 13b-i?

Copy and paste relevant sections from the manuscript or cite the figure number if applicable (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Participants received the messages for 6 months, they could not continue after this time.
14a) Dates defining the periods of recruitment and follow-up

Does your paper address CONSORT subitem 14a?*

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

*Participants were recruited from 16 general practices in England between January 2019 and June 2019."

14a-i) Indicate if critical “secular events” fell into the study period

Indicate if critical “secular events” fell into the study period, e.g., significant changes in Internet resources available or “changes in computer hardware or Internet delivery resources”

Does your paper address subitem 14a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not relevant for a text message intervention.

14b) Why the trial ended or was stopped (early)
Does your paper address CONSORT subitem 14b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The trial ended after the planned amount of time as specified in the protocol [22]

15) A table showing baseline demographic and clinical characteristics for each group
NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group

Does your paper address CONSORT subitem 15? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes, Table 3 provides this information

15-i) Report demographics associated with digital divide issues
In ehealth trials it is particularly important to report demographics associated with digital divide issues, such as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the participants, if known.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 15-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes, Table 3 provides this information
16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

16-i) Report multiple “denominators” and provide definitions
Report multiple “denominators” and provide definitions: Report N's (and effect sizes) “across a range of study participation [and use] thresholds” [1], e.g., N exposed, N consented, N used more than x times, N used more than y weeks, N participants “used” the intervention/comparator at specific pre-defined time points of interest (in absolute and relative numbers per group). Always clearly define “use” of the intervention.

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| subitem not at all important | | | | | essential |

Does your paper address subitem 16-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This information is provided in the CONSORT flow diagram.

16-ii) Primary analysis should be intent-to-treat
Primary analysis should be intent-to-treat, secondary analyses could include comparing only "users", with the appropriate caveats that this is no longer a randomized sample (see 18-i).

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| subitem not at all important | | | | | essential |

Clear selection
17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

Does your paper address CONSORT subitem 17a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

ANCova results reported in line with APA advice

17a-i) Presentation of process outcomes such as metrics of use and intensity of use

In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous exposure metrics such as “average session length”. These must be accompanied by a technical description how a metric like a “session” is defined (e.g., timeout after idle time) [1] (report under item 6a).

1 2 3 4 5

subitem not at all important ● ○ ○ ○ ○ essential

Clear selection

Does your paper address subitem 17a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not relevant to this paper.
17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT subitem 17b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No binary outcomes reported

18) Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

Does your paper address CONSORT subitem 18? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Sensitivity analysis treating baseline variables as covariates rather than as within-subject factors showed aligned significant or nonsignificant effects for 12 of the 14 constructs measured. Previously significant effects on recovery self-efficacy (P=.12) and maintenance self-efficacy (P=.30) were not replicated."

18-i) Subgroup analysis of comparing only users
A subgroup analysis of comparing only users is not uncommon in ehealth trials, but if done, it must be stressed that this is a self-selected sample and no longer an unbiased sample from a randomized trial (see 16-iii).

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Clear selection
Does your paper address subitem 18-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No distinction between 'users' and 'non-users' in this case. Use of the intervention required receiving text messages.

19) All important harms or unintended effects in each group
(for specific guidance see CONSORT for harms)

Does your paper address CONSORT subitem 19? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No harm reported from receiving text messages.

19-i) Include privacy breaches, technical problems

Include privacy breaches, technical problems. This does not only include physical "harm" to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. "Unintended effects" also includes unintended positive effects [2].

|   | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| subitem not at all important | ○ | ○ | ☐ | ○ | ○ |

Clear selection

Does your paper address subitem 19-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

There were no privacy breaches or technical problems
19-ii) Include qualitative feedback from participants or observations from staff/researchers

Include qualitative feedback from participants or observations from staff/researchers, if available, on strengths and shortcomings of the application, especially if they point to unintended/unexpected effects or uses. This includes (if available) reasons for why people did or did not use the application as intended by the developers.

1 2 3 4 5
subitem not at all important

Does your paper address subitem 19-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not relevant for this paper

DISCUSSION

22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
NPT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group
22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)

Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use).

1 2 3 4 5

subitem not at all important o o o o o essential

Clear selection

Does your paper address subitem 22-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Principal Results

In this analysis we have shown that first, provision of a text message-based intervention using behavior change techniques results in improvements to multiple psychological constructs compared to usual care. Second, we have identified that changes in psychological constructs are correlated with changes in self-reported medication adherence. These findings support the hypothesized mechanisms of action that are amenable to change through a low-cost, scalable intervention, and that when changed, may have an effect on medication adherence in people with type 2 diabetes. These findings, although tentative, provide a strong base on which to progress to a full efficacy trial."

22-ii) Highlight unanswered new questions, suggest future research

Highlight unanswered new questions, suggest future research.

1 2 3 4 5

subitem not at all important o o o o o essential

Clear selection
Does your paper address subitem 22-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

*Future Development
Future research could use these findings for the following purposes: to investigate those constructs that did not change in this instance, and whether there are more effective BCTs to target these constructs than those used here; to explore those constructs where changes did not correlate with changes in medication adherence; and to improve the measurement of constructs where correlations between the 2 items were weak. This work would help to gather additional information that could be used to optimize interventions for this population.

The findings reported indicate that certain constructs are both amenable to change by text message and, when changed, are associated with changes in self-reported medication adherence (eg, intention, maintenance self-efficacy, and satisfaction with experienced consequences). These constructs could indicate the importance of continued feedback and adjustment within medication adherence interventions; following initial changes to intention, it may be necessary to support people to maintain and highlight the positive effects of changes made to support satisfaction with continued adherence. BCTs that target these constructs may be useful for focusing on future research into medication adherence.

This feasibility trial was not powered to look at direct effects of the intervention on the outcome. The findings do provide a clear indication of the potential value of an intervention such as this, but in the planned trial of this intervention participant numbers will be sufficiently high to ascertain efficacy of the intervention and allow for mediation analysis to further explore the potential mechanisms of action suggested here. By identifying likely mechanisms of action of the intervention beforehand, efficacy results will be more easily interpreted. In addition, with a larger sample, it may be possible to conduct subanalysis to explore whether changes in constructs are associated with particular participant characteristics, and this could provide evidence to inform future tailoring strategies. Incorporating tailoring increases the complexity of an intervention and potentially reduces the scalability. However, if future tailored interventions were compared with this nontailored intervention, an evidence base could be built on how to tailor in the most effective way, which would only introduce additional complexity where there is likely to be maximum benefit."

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
20-i) Typical limitations in ehealth trials

Typical limitations in ehealth trials: Participants in ehealth trials are rarely blinded. Ehealth trials often look at a multiplicity of outcomes, increasing risk for a Type I error. Discuss biases due to non-use of the intervention/usability issues, biases through informed consent procedures, unexpected events.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Clear selection
Does your paper address subitem 20-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

*Strengths and Weaknesses

The intervention messages use a wide variety of BCTs that are thought to target different points in the process of adherence. The incorporation of a wide variety of techniques, including some BCTs that have not been applied in this context previously, constitutes one of the strengths of this intervention, as this represents a new way to approach medication adherence. However, a corresponding weakness is that this could make looking at each individual link between BCTs and constructs more difficult, as several BCTs might have affected the same construct.

These findings have shown that this intervention can have an effect on multiple constructs that may influence people at different points in the process of improving medication adherence from forming an intention, acting on that intention, to monitoring and adjusting these actions until adherence becomes habitual (see Figure 1). In addition, the intervention targets sources of both intentional and nonintentional nonadherence. The potential to affect change in people wherever they are in the process of improving medication adherence is a definite strength, from which a wide range of people with type 2 diabetes can benefit. In this feasibility study, we were not powered to conduct a formal mediation analysis, however this is planned for the definitive trial which is now underway (ISRCTN 15952379).

Medication adherence has been self-reported here using the MARS. In the future, we plan to take additional measures of adherence (eg, from medical records) so that the relationships between these constructs, self-reported adherence, and adherence measured through more direct means can be explored. Future work could also explore the use of objective measures of medication adherence, such as urine samples [33]. Overall, this study provides a more detailed picture of the potential mechanism of action for this intervention, which can be used to support development of further interventions for this target behavior.

The eventual aim is that the brief text message intervention can be delivered at scale, through general practice. In terms of future scalability, basing the intervention solely on text messages is highly cost-effective. Recent research has indicated combining text messages with interactive voice recognition can be an effective intervention for medication adherence in this population [34]; there is further evidence that incorporating tailoring can make interventions more effective [13]. Any additional components and technology required above and beyond text messages, and any additional complexity may limit the eventual scalability of the intervention. Understanding the unique effects of nontailored text messages alone in the first instance is useful, as this is the lowest-cost approach. Additional elements could then be added to the intervention where they would provide the most benefit and when the evidence is clearer on which conditions tailoring can be optimally applied to.

The measures of psychological constructs used in this study were by necessity brief to minimize participant burden. There is increasing recognition that high questionnaire burden in trials has undesirable consequences, such as reducing recruitment, increasing dropout in low socioeconomic status or minority ethnic groups, and producing unintended reactions to this measurement [35]. It was therefore necessary to use a questionnaire developed for this study. Items from pre-existing scales were used when possible, and the correlations for the majority of items were considered moderately or strongly correlated [36]. However, there
were 3 constructs with weak correlations between items (concerns, action control, and social support), and we aim to improve these items for our future research. An alternative approach could be to use this preliminary work to identify specific constructs of interest and measure a smaller number of constructs with validated scales.

21) Generalisability (external validity, applicability) of the trial findings
NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

21-i) Generalizability to other populations
Generalizability to other populations: In particular, discuss generalizability to a general Internet population, outside of a RCT setting, and general patient population, including applicability of the study results for other organizations

| Subitem | 1 | 2 | 3 | 4 | 5 |
|---------|---|---|---|---|---|
| Not at all important |   |   |   |   |   |
| Essential |   |   |   |   |   |

Clear selection

Does your paper address subitem 21-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer
21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting

Discuss if there were elements in the RCT that would be different in a routine application setting (e.g., prompts/reminders, more human involvement, training sessions or other co-interventions) and what impact the omission of these elements could have on use, adoption, or outcomes if the intervention is applied outside of a RCT setting.

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| subitem not at all important |   |   |   | essential |

Clear selection

Does your paper address subitem 21-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The eventual aim is that the brief text message intervention can be delivered at scale, through general practice. In terms of future scalability, basing the intervention solely on text messages is highly cost-effective."

OTHER INFORMATION

23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

ISRCTN Registry ISRCTN13404264; https://www.isrctn.com/ISRCTN13404264

24) Where the full trial protocol can be accessed, if available
25) Sources of funding and other support (such as supply of drugs), role of funders

Does your paper address CONSORT subitem 25? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

*The authors would like to acknowledge the support of the University of Oxford Primary Care Clinical Trials Research Unit; the National Institute for Health Research (NIHR); Greater Manchester, West Midlands, South West Peninsula and Thames Valley, and South Midlands Clinical Research Networks; participating general practitioner surgeries; and the SuMMiT-D team.

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X27) Conflicts of Interest (not a CONSORT item)
X27-i) State the relation of the study team towards the system being evaluated

In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ○ essential

Clear selection

Does your paper address subitem X27-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Conflicts of Interest
None declared."

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As a result of using this checklist, did you make changes in your manuscript? *

○ yes, major changes
○ yes, minor changes
○ no

What were the most important changes you made as a result of using this checklist?

Your answer
How much time did you spend on going through the checklist INCLUDING making changes in your manuscript *

1 - 1.5 hours. The checklist was sent at a very late stage. The manuscript has already been through peer review and 2 rounds of copy-editing.

As a result of using this checklist, do you think your manuscript has improved? *

- yes
- no
- Other:

Would you like to become involved in the CONSORT EHEALTH group?

This would involve for example becoming involved in participating in a workshop and writing an "Explanation and Elaboration" document

- yes
- no
- Other:

Any other comments or questions on CONSORT EHEALTH

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