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

* Required
Your name *
First Last
Chandra

Primary Affiliation (short), City, Country *
University of Toronto, Toronto, Canada
Lirio, Nashville, United States

Your e-mail address *
abc@gmail.com
consultcyo@gmail.com

Title of your manuscript *
Provide the (draft) title of your manuscript.
Randomized Control Trial: One Drop with an Activity Tracker Lowers the A1c of Adults with Type 1 Diabetes

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.
One Drop

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

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

abetes-management/id972238816 and

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)"

Diabetes

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

Hemoglobin A1c
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:

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%
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:

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: JMU ms#16745
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:

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.

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

The mode of delivery is implied in the title. "Randomized Control Trial: One Drop with an Activity Tracker Lowers the A1c of Adults with Type 1 Diabetes"

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").
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.

n/a

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

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.

"Randomized Control Trial: One Drop with an Activity Tracker Lowers the A1c of Adults with Type 1 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/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT
Mention key features/functionalities/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)
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.

"Participants (N = 99) were randomized to get OD plus activity tracker at study start or OD at start and an activity tracker after 3 mos." OD = One Drop

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)

"We conducted a pragmatic, remotely-administered, randomized control trial to evaluate One Drop with an activity tracker on the A1c of adults with T1D."

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)
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.

"Social media advertisements and online newsletters recruited adults (≥ 18 years old) diagnosed (≥ 1 year) with T1D, naïve to OD’s full solution and the activity tracker with lab A1c ≥ 7%.

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)

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.

"In ITT and PP (with most OD engaged and complete data [n=77]), OD + tracker had a lower 3-mo than OD alone when baseline A1c was > 7% to ≤ 10% (ITT A1c MeanDiff .35% to .51%, p = .01 to .05 and PP A1c MeanDiff .27% to .47%, p = .02 to .05)." i.e., n=77 of 95 enrolled participants used the intervention as intended.

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)
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

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)

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

"Adults with T1D use the One Drop | Mobile smartphone app without and with activity trackers (e.g., Apple Watch [17, 18]) [16]. One Drop’s app reads and displays activity data from trackers and other devices, and is rated among the top three diabetes apps in the world [19]. The One Drop | Chrome Bluetooth-connected meter syncs and displays blood glucose readings in the app. One Drop’s Certified Diabetes Educators (‘coaches’) remotely monitor user data and offer in-app education, strategies, and support. In observational studies, people with T1D or type 2 diabetes using One Drop’s app on Apple Watch averaged a -1.2 to -1.3% absolute A1c improvement [17, 18]."
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.

"Studies consistently associate using One Drop with improved A1c, but none to date have been randomized control trials or included people with T1D using an activity tracker or smartwatch."

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.

"We conducted a three-month prospective, randomized control trial to evaluate the effect of One Drop and an activity tracker on the A1c of people with T1D."

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.

"The study design was a pragmatic, parallel group, randomized control trial."

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.

"There were no methodological changes during the trial period."

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].

subitem not at all important

1  2  3  4  5

essential

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.

"As is the case with all apps, occasional minor bug fixes are typical. None resulted in major system failures or downtimes during the trial period."

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

"Initially eligible persons met criteria on the online, screening survey. They self-reported age 18-75 years, a valid U.S. mailing address, a diagnosis of T1D for more than one year, not currently participating in a diabetes education or coaching program, not pregnant or planning to become pregnant, using an Android or iOS smartphone, and never having used the activity tracker and One Drop (no app activity, 7-day trial, testing supply subscription, or coaching)." For people who screened initially eligible, "DTI laboratories shipped an AccuBase A1c test kit to each respondent’s mailing address. People with an A1c greater than or equal to 7% were considered eligible for the study, randomized to condition, and notified of their A1c test result and condition assignment."

4a-i) Computer / Internet literacy
Computer / Internet literacy is often an implicit "de facto" eligibility criterion - this should be explicitly clarified.

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

As noted above, "using an Android or iOS smartphone" was required for participation in the study.

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.
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.

"Once respondents electronically signed both forms, they landed on an online, HIPAA-compliant baseline survey. Upon completing the baseline survey, DTI laboratories shipped an AccuBase A1c test kit to each respondent’s mailing address. Study personnel provided written, illustrated, and video A1c test kit instructions and offered over-the-phone help with collecting a blood sample. People returned blood samples to the lab in a pre-addressed and pre-stamped box. The lab processed each sample and uploaded results into a HIPAA-compliant online portal. Study personal reviewed each result to determine A1c eligibility. After three months, all participants received an initial and series of reminder emails instructing them to complete an online, HIPAA-compliant follow-up survey with an embedded hyperlink in the email. Upon completing this survey, DTI laboratories mailed participants a second, final A1c test kit. Again, study personnel sent instructions in various formats along with study contact information to aid with collecting a blood sample. Participants returned blood samples in a pre-addressed and pre-stamped box. The lab processed each sample and uploaded results into the HIPAA-compliant online portal."

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

"Facebook advertisements and One Drop’s email list of non-customers (i.e., people without a One Drop meter and testing supplies, or a coach) remotely recruited potential participants from March through May 2018. Online advertisements and email messages briefly described study eligibility (e.g., diagnoses of type 1), study scope (e.g., 3-month duration), and asked people interested in the study to click a link to get in-depth information about the study and complete an online, HIPAA-compliant survey to self-screen for initial eligibility. People self-screening eligible ... landed on an electronic IRB-approved consent form and HIPAA authorization form, requiring review and signature. All respondents were invited to contact study personnel to receive a verbal explanation of the forms and/or get any study-related questions answered."

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

"...self-reported surveys were self-administered via online, HIPAA-compliant surveys and forms. Participants used a mail-in A1c test to self-collect and supply two blood specimens. Study personnel provided virtually-disseminated instruction and support (via phone and email) to remotely eligible participants into their respective conditions. Only participants accessing all intervention components were considered enrolled."

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.
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.

"Once respondents electronically signed both forms, they landed on an online, HIPAA-compliant baseline survey. Upon completing the baseline survey, DTI laboratories shipped an AccuBase A1c test kit to each respondent’s mailing address. Study personnel provided written, illustrated, and video A1c test kit instructions and offered over-the-phone help with collecting a blood sample. People returned blood samples to the lab in a pre-addressed and pre-stamped box. After three months, all participants received an initial and series of reminder emails instructing them to complete an online, HIPAA-compliant follow-up survey with an embedded hyperlink in the email. Upon completing this survey, DTI laboratories mailed participants a second, final A1c test kit. Again, study personnel sent instructions in various formats along with study contact information to aid with collecting a blood sample."

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)

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.

The informed consent document listed the study investigator names and affiliations.

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).

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

n/a - this information is publicly available

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.

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

n/a - this, too, is publicly available

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).
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.

"The digital therapeutics solution includes the accurate FDA-approved One Drop | Chrome Bluetooth-connected blood glucose meter [20] and testing supplies, One Drop | Mobile app, and One Drop coaching programs. One Drop coaches are CDEs providing the first digitally-delivered diabetes education accredited by the American Diabetes Association. One Drop’s evidenced-based app [8] is available on iOS, Android, watchOS, and Amazon’s Alexa and has been downloaded in every country in the world. Features include reminders to perform and track self-care, a ‘Community’ section to bolster normative support, and education and skills training via the dynamic ‘Newsfeed’ section and coaching chat section and programming content. Data reports can be viewed in the app, printed, and emailed."

5-iv) Quality assurance methods

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

"Quality assurance efforts identified two participants ineligible for the study (i.e., they had used One Drop before) that we excluded from all analyses (n = 1 in OD + activity tracker and n = 1 in OD only), resulting in 95 participants in ITT and 77 participants in PP."
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 | O | | | | |
| essential | | | | | |

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

n/a - this information is proprietary

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](http://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 | O | | | | |
| essential | | | | | |

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

n/a - the intervention is a suite of consumer health technologies available in the public domain
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).

subitem not at all important

1  2  3  4  5

essential
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.

"Study personnel provided virtually-disseminated instruction and support (via phone and email) to remotely eligible participants into their respective conditions."

"Once randomized to condition, eligible participants received an email message containing their condition assignment, a series of instructions, and unique verification code. The email message instructed participants to first download the One Drop | Mobile app on iOS or Android with embedded links to both formats for direct access. Next, participants were instructed to open the One Drop app, create an account, enter their unique coaching verification code (from the email). Finally, participants were given a link to One Drop’s online store and instructed to trigger a no cost shipment of the activity tracker, One Drop | Chrome meter, and testing supplies for the three-month study period. When needed, study personnel assisted participants with completing these steps via a phone call and/or email exchange.

One Drop + activity tracker at study start (OD + tracker). Participants assigned to the OD + tracker condition were mailed an activity tracker, One Drop | Chrome meter and testing supplies. Upon receipt, participants were instructed to use the One Drop app to connect with their coach, create an activity tracker account and link it to their One Drop account, and download the tracker-compatible One Drop app. Finally, participants were instructed to use the app, meter, in-app coaching and activity tracker ‘as needed’ for the three-month study period.

One Drop + activity tracker at study end (OD only). Participants assigned the OD only condition were mailed the One Drop | Chrome meter and testing supplies. The activity tracker shipped after completing the follow-up survey and A1c test. Participants connected with their One Drop coach via the One Drop app, and were instructed to use the app, meter, and in-app coaching ‘as needed’ for the three-month study period."
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].

Does your paper address subitem 5-viii? *

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

"One Drop. The digital therapeutics solution includes the accurate FDA-approved One Drop | Chrome Bluetooth-connected blood glucose meter [20] and testing supplies, One Drop | Mobile app, and One Drop coaching programs. One Drop coaches are CDEs providing the first digitally-delivered diabetes education accredited by the American Diabetes Association. One Drop’s evidenced-based app [8] is available on iOS, Android, watchOS, and Amazon’s Alexa and has been downloaded in every country in the world. Features include reminders to perform and track self-care, a ‘Community’ section to bolster normative support, and education and skills training via the dynamic ‘Newsfeed’ section and coaching chat section and programming content. Data reports can be viewed in the app, printed, and emailed."

"Activity tracker. The wrist-worn device tracks activity and swimming, monitors heart rate, includes a built-in GPS, and real-time stats (e.g., pace and distance), phone free music to exercise with, and personalized workouts. With each workout, software learns about a user’s fitness level, makes personalized recommendations and gives dynamic feedback. Third party app developers like One Drop can make device-compatible apps. One Drop’s app on the device is an at-a-glance display of the last minutes of activity, grams of carbohydrates, blood
at a glance display of the last minutes of activity, grams of carbohydrates, blood glucose reading, and medications taken."

5-ix) Describe use parameters
Describe use parameters (e.g., intended “doses” and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.

Does your paper address subitem 5-ix?
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 - people use consumer health technologies as needed in a variety of ways; there is no recommended dose; 'as needed' dosing is mentioned in the paper

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).

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.

“Study personnel provided virtually-disseminated instruction and support (via phone and email)."
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).

subitem not at all important

1 2 3 4 5

essential

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

"After three months, all participants received an initial and series of reminder emails instructing them to complete an online, HIPAA-compliant follow-up survey with an embedded hyperlink in the email. Upon completing this survey, DTI laboratories mailed participants a second, final A1c test kit. Again, study personnel sent instructions in various formats along with study contact information to aid with collecting a blood sample."

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).

subitem not at all important

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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

n/a
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.

"Glycated hemoglobin A1c (A1c). Self-administered AccuBase A1c Mail-In Test Kits (DTI Laboratories, Thomasville, GA) assessed baseline and follow-up A1c levels. The test is FDA-approved, NGSP-certified and CLIA-waived and a highly accurate assessment of A1c used in randomized and non-randomized trials [21, 22]. It is a non-fasting, finger stick, whole blood mail-in test. Upon supplying a blood sample, specimens are processed at a central lab."

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].

Does your paper address subitem 6a-i?

n/a - only self-reported demographic and health status data (e.g., number of years since being diagnosed with type 1 diabetes and body mass index) are included, not data from valid and reliable questionnaires

6a-ii) Describe whether and how “use” (including intensity of use/dosage) was defined/monitored

Describe whether and how “use” (including intensity of use/dosage) was defined/monitored (logins, logfile analysis, etc.). Use/adoption metrics are important process outcomes that should be reported in any ehealth trial.

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

n/a - people use consumer health technologies as needed in a variety of ways; there is no recommended dose; 'as needed' dosing is mentioned in the paper

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 |

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

n/a - participants' qualitative feedback are not reported

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

n/a - there were no changes

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 | 1 | 2 | 3 | 4 | 5 |
|---------|---|---|---|---|---|
| Not at all important | ○ | ○ | ○ | ○ | ○ |

Does your paper address subitem 7a-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.

n/a - the sample size used in prior diabetes studies with the activity tracker informed the target sample of ~100 eligible participants randomized to two conditions.

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

n/a

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

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.

"We used an online randomizer to block randomize..."
8b) Type of randomisation; details of any restriction (such as blocking and block size)

Does your paper address CONSORT subitem 8b? *
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

"Study personnel used a block randomization scheme of 100 groups of two randomization blocks to randomize participants to one of two conditions."

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

n/a - the study was unblinded

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

"Study personnel used a block randomization scheme of 100 groups of two randomization blocks to randomize participants to one of two conditions."

11a) If done, who was blinded after assignment to interventions

We used an online randomizer to block randomize...
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).

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| 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

"Participants and study personnel were unblinded to condition assignment."

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”.

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| subitem not at all important | | | | | essential |

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

"Study personnel did not tell participants which condition was the intervention of interest and which one was the comparator, but participants may have inferred this on their own."

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 comparison intervention with an active 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.

There were "two conditions: (1) One Drop’s digital therapeutics solution (i.e., the mobile app, in-app coaching, Bluetooth-connected meter with a 3-month supply of test strips) and an activity tracker at the start of the intervention period or (2) One Drop at the start of the intervention period and an activity tracker after completing follow-up measures."

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.

"Analysis of covariance (ANCOVA) models [26] tested the group effect on follow-up A1c controlling for baseline A1c. For non-crossover, parallel group RCTs, CONSORT guidelines recommend reporting results from ITT and PP analyses [27, 28]. ITT preserves baseline group assignment and avoids over-estimating group effects [29]. In contrast, PP may exaggerate group effects by including only participants receiving the allocated intervention and completing the study as intended [30, 31]. In pragmatic trials, the appropriate reporting of both results can aid with scientific and clinical interpretation [32]. We examined ANCOVA assumptions before conducting ANCOVA models testing follow-up A1c, group differences."

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]).
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.

"Multiple imputation corrected for missing data [25] on income (n = 4) and follow-up A1c (n = 10). In both conditions, variables used to impute included non-missing age, gender race/ethnicity, education, insurance status, diabetes duration, baseline BMI and A1c, and available data on income. Data were imputed separately by study condition. Imputed data were constrained by condition-specific minimum and maximum values. There were 20 imputations per condition. Data were merged prior to conducting intent-to-treat (ITT) and per protocol (PP) analyses."

n/a - there were no subgroup 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.

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.
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.

Does your paper address subitem X26-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

"They landed on an electronic IRB-approved consent form and HIPAA authorization form, requiring review and signature. All respondents were invited to contact study personnel to receive a verbal explanation of the forms and/or get any study-related questions answered."

X26-iii) Safety and security procedures

Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

Does your paper address subitem X26-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

"Solutions IRB approved all study procedures prior to recruiting participants." and "Study instructions, consent and HIPAA authorization forms, and self-reported surveys were self-administered via online, HIPAA-compliant surveys and forms."
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

"As shown in the CONSORT diagram (See Figure 1), 491 people self-screened for initial eligibility; 417 screened initially eligible, completed informed consent, HIPAA authorization, and the baseline survey, and were shipped an A1c test kit. A total of 363 people returned the kit with a blood sample; 99 satisfied A1c ≥ 7% eligibility criteria and were randomized to the OD + tracker or OD only conditions; 97 received the intervention, defined as downloading the app and initiating coaching." and "Quality assurance efforts identified two participants ineligible for the study (i.e., they had used One Drop before) that we excluded from all analyses (n = 1 in OD + activity tracker and n = 1 in OD only), resulting in 95 participants in ITT and 85 participants in PP."

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. See Figure 1.

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.
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

Yes. See Figure 1.

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

"Recruitment and enrollment occurred from March through May 2018, and the last follow-up was in August 2018."

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

n/a

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
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? *

"Descriptive statistics summarized the intent-to-treat sample at baseline (N = 95). The sample was 40.9 +/- 10.7 years old (See Table 1). The majority were female (73%), Caucasian / White race (88%), had at least some college education (77%), an annual household income greater or equal than 50K (56%), and/or were overweight or obese (80%). The sample was diagnosed with T1D an average 20.3 +/- 11.5 years ago and had an average baseline A1c of 8.41% +/- 1.18%.

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

Does your paper address subitem 15-i? *

Yes. See above and Table 1.

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.

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| 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

Yes. See Table 1.

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).

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| subitem not at all important |   |   |   |   | essential |
The assumption of homogeneity of regression slopes was not met (F-pooled = 117.84, p < .001) requiring examination of effects by different baseline A1c levels and conducting four Bonferroni-corrected t-tests (p < .01). T-tests were pooled with imputed data, i.e., follow-up A1c. T-tests examined A1c group differences at baseline, follow-up, and from baseline to follow-up for each group, separately.

A higher baseline A1c was associated with a better effect from OD + tracker than OD only (See Table 2 and Figure 2). A1c did not differ between groups at baseline (t = .49, p = 0.62) or follow-up (t-pooled = -1.26, p = .22). The OD + activity tracker group's A1c significantly improved from baseline to follow-up (8.47% v. 8.04%, .43% absolute change, t-pooled = 4.72, p < .001) whereas the OD only group's A1c did not change over time (8.35% v. 8.33%, .02% absolute change, t-pooled = .23, p = .82)." Also, see Table 2."
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).

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

n/a - people use consumer health technologies as needed in a variety of ways; there is no recommended dose; 'as needed' dosing is mentioned in the 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

n/a - the outcome is continuous

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
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).

Does your paper address subitem 18-i?

A requirement for participation was "never having used the activity tracker and One Drop (no app activity, 7-day trial, testing supply subscription, or coaching)." In this way, all participants included in analyses were non-users.

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

Does your paper address CONSORT subitem 19? *

"Study participation resulted in no reported harms, unintended effects, or adverse events."

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].
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

All aspects of the study were HIPAA-compliant. "There were also no privacy breaches, severe technical problems, or unexpected/unintended incidents during the study."

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.

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

From the study team, "...data collection and analyses were completed in 6.4 months, saving time, money, and providing just-in-time results to decision makers. It takes 17 years to turn 14% of research findings into benefits for patients [39]. This trial strongly challenges how long it takes to conduct a randomized control trial and translate results into the real-world."

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

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

"This is the first randomized control trial evaluating One Drop with an activity tracker on the A1c of adults with T1D. For participants with an 8-11% A1c at baseline, using One Drop with an activity tracker led to a significantly lower three-month A1c compared to using One Drop only. Both intent-to-treat and per protocol analyses (i.e., among participants using all aspects of One Drop who also provided a follow-up) yielded this significant A1c benefit."

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

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

"Results from this trial suggest One Drop and an activity tracker may work better together than alone in helping people with T1D. Additional research with a tracker only arm is needed to substantiate this finding."
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.

subitem not at all important 1 2 3 4 5 essential

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

"The trial's predominantly female (73%) and overweight/obese (80%) sample may have been uniquely engaged and activated by using a tracker with One Drop. Results may not generalize to adults with T1D that are male and/or have a 'normal' BMI."

"...this trial was 'pragmatic'[38]. Study procedures were conducted remotely in the context of participant's everyday life, maximizing the applicability and generalizability of the findings. A more controlled environment may have produced more internally valid results, but at the cost of less generalizability."

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 not at all important 1 2 3 4 5 essential
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.

"This trial was far-reaching and representative, with people of different race/ethnicities, social classes, and education levels participating from 43/50 states."

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.

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.

"While the pragmatic and remote study design allowed for recruitment, data collection, and participation to occur in the context of everyday life, making it more convenient than trials requiring study visits at clinical trial sites, remoteness also meant relying on self-reported screening data, and medication and medical history."

23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *
24) Where the full trial protocol can be accessed, if available

Does your paper address CONSORT subitem 24? *
Cite a Multimedia Appendix, other reference, or 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.

Additional study details, design, and outcomes are publicly available on https://clinicaltrials.gov/ct2/show/NCT03459573

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.

No. The activity tracker company wishes to remain anonymous.

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
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

"Chandra Osborn and Lindsay Sears were full-time employees of Informed Data Systems Inc. (IDS), manufacturer of One Drop's digital therapeutics solution, during the conduct of this research. Ashley Hirsch, Mark Heyman, Brian Huddleston, and Jeff Dachis are currently full-time employees and have stock in IDS. Jennifer Raymond is a member of One Drop's clinical advisory board."

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 *

8 hours
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

n/a

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