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 multiplier 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 copied, 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):

Epsteinbach 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: 2209829

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First Last

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

Effectiveness of a web-based menu-planning intervention to improve childcare service compliance with dietary guidelines: a randomised controlled trial.

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.

feedAustralia

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

Your answer

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.

Your answer

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)”

Implementation of dietary guidelines in:

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

Mean number of food groups on menu c
Secondary/other outcomes
Are there any other outcomes the intervention is expected to affect?

Menu compliance with guidelines for all food groups; Individual food group compliance with dietary guidelines; Mean servings of individual food groups

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: Not specified

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: "As recommended" was not specified to users

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: Significant improvement in the intervention group compared to cont
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:

TITLE AND ABSTRACT

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

1a) Does your paper address CONSORT item 1a? *
Is 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" (3D 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 "i-phone"), especially if the application runs on different platforms.

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

"Effectiveness of a web-based menu-planning intervention to improve childcare service compliance with dietary guidelines: a randomised controlled trial"

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").

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

Your answer

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

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

"Effectiveness of a web-based menu-planning intervention to improve childcare service compliance with dietary guidelines: a randomised controlled trial"

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

"Services were randomised to a 12 month intervention or usual care control. Intervention services received access to an online menu planning program linked to their usual child care management software system."

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)

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

Your answer

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 user group 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 indicate 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

Your answer
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)

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.

Your answer

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)

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.

Your answer

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 S)

subitem not at all important ○ ○ ○ ○ ○ essential
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.

“Foods provided in childcare services are not consistent with dietary guideline recommendations.

Despite the potential, the effectiveness of a web-based intervention to improve childcare service implementation of dietary guidelines has not yet been evaluated [32]. As such, the primary aim of the study was to assess, compared to usual care, the effectiveness of a web-based menu planning intervention in increasing the mean number of food groups on childcare service menus that comply with dietary guidelines. Secondary aims include assessment of the impact of the intervention on: i) the proportion of service menus compliant with i) all food groups; ii) individual food groups; and iii) the mean servings of individual food groups. Childcare service use and acceptability of the web-based program was also assessed.”

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 [3]. 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.

“Online interventions offer an opportunity to provide implementation support that has the potential to be effective in enhancing childcare service implementation of dietary guidelines. Firstly, childcare services have existing infrastructure (computer and internet access) to support an online intervention [27], and staff are willing to use such an intervention to support their implementation of healthy eating policies and practices [27]. Secondly, specific programming within online systems [28] has the potential to integrate active behaviour change strategies [29] to target primary barriers to guideline implementation, including audit and feedback for menus, automated calculation of menu compliance, eliminating the need for manual calculations by service staff, and online resources. Thirdly, online interventions can be tailored to a particular service’s needs, and delivered with high fidelity, at low end-user cost, and are able to address equity issues related to access to dietetic support, in particular for childcare services in rural and remote areas [30, 31]. Finally, online systems have the potential to minimise the need for ongoing investment in implementation support (e.g. the provision of training and resources) in order for practice improvements to be sustained.”

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

"As such, the primary aim of the study was to assess, compared to usual care, the effectiveness of a web-based menu planning intervention in increasing the mean number of food groups on childcare service menus that comply with dietary guidelines. Secondary aims include assessment of the impact of the intervention on: the proportion of service menus compliant with i) all food groups; ii) individual food groups; and iii) the mean servings of individual food groups. Childcare service use and acceptability of the web-based program was also assessed."

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

"a parallel group randomised controlled trial"

"Following the completion of baseline data collection, services were allocated to the intervention or control group in a 1:1 ratio, stratified by socioeconomic status (as determined by service postcode) [37] by an independent statistician using a random number function in Microsoft Excel 2010."

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

Prior to trial commencement: "The menu planning intervention was not embedded within the CCMS platform already used by the childcare services as originally planned due to changes in national regulatory requirements for CCMS. Rather, the menu planning program was developed as a stand-alone program, allowing childcare services to access the intervention outside of CCMS. The program was linked to the online web-based CCMS platform to allow communication between the two systems."

NA after 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-ii) and other "unexpected events" that may have influenced study design such as staff changes, system failures/downtimes, etc. [2]

subitem not at all important  ○  ○  ○  ○  ○  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.

Your answer

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 childcare services were required to: i) be open for 28 hours each weekday; ii) prepare and provide at least one main meal and two snacks to children onsite each weekday; iii) have service staff make menu planning decisions; and iv) have a menu planner with sufficient English to engage with the intervention. Services that outsourced menu planning, did not cater for children aged 3-6 years, catered exclusively for special needs children, or were run by the NSW Department of Education were excluded due to differing administrative characteristics."

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

| Subitem not at all important | 0 | 0 | 0 | 0 | 0 | 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.

Your answer

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 did the study team 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.

| Subitem not at all important | 0 | 0 | 0 | 0 | 0 | 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.

"All services in the sampling frame were posted an invitation letter and information statements about the study in random order, approximately two weeks prior to receiving a call from a research assistant to assess eligibility and obtain service consent to participate (August – December 2017). Recruitment of services was conducted in random order as a sub-sample of services also participated in a nested evaluation [34]. The CCMS provider also displayed an invitation for services to participate in the trial via their online access 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 X2b), as this information may have an effect on user self-selection, user expectation and may also bias results.

subitem not at all important ○ ○ ○ ○ ○ essential

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

Your answer

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

"Following provision of consent, nominated supervisors and menu planners were recontacted to complete a computer assisted telephone interview (CATI) to assess baseline service and menu planner characteristics, and were asked to provide a one-week long menu from their current menu cycle for assessment."

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.

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

"Following provision of consent, nominated supervisors and menu planners were recontacted to complete a computer assisted telephone interview (CATI) to assess baseline service and menu planner characteristics, and were asked to provide a one-week long menu from their current menu cycle for assessment."

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)

subitem not at all important ○ ○ ○ ○ ○ essential

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

Your answer
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 [5] (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.

Your answer

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.

Your answer

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.

Your answer

5-iv) Quality assurance methods
Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.

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.

Your answer
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.

Your answer

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.

subitem not at all important ○ ○ ○ ○ ○ 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.

Your answer

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.

subitem not at all important ○ ○ ○ ○ ○ 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.

Your answer

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 ○ ○ ○ ○ ○ 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

"Services received a 12 month implementation intervention consisting of access to a web-based menu planning tool, in addition to training and support to use the program (Table 1). The menu planning intervention was not embedded within the CCMS platform already used by the childcare services as originally planned due to changes in national regulatory requirements for CCMS. Rather, the menu planning program was developed as a stand-alone program, allowing childcare services to access the intervention outside of CCMS. The program was linked to the online web-based CCMS platform to allow communication between the two systems."

Participants did not pay to use the program.

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

"Services received a 12 month implementation intervention consisting of access to a web-based menu planning tool, in addition to training and support to use the program (Table 1). The menu planning intervention was not embedded within the CCMS platform already used by the childcare services as originally planned due to changes in national regulatory requirements for CCMS. Rather, the menu planning program was developed as a stand-alone program, allowing childcare services to access the intervention outside of CCMS. The program was linked to the web-based CCMS platform to allow communication between the two systems. The intervention was co-developed and overseen by an experienced multi-disciplinary expert advisory group consisting of health promotion practitioners, implementation and behavioural scientists, policy makers, and public health nutritionists with experience working in the setting. To ensure uptake and enhance use of the web-based program, the menu planning program was developed using the Technology Acceptance Model [38], with implementation support strategies identified through barriers assessment using the Theoretical Domains Framework [39]. Further details regarding the theoretical underpinnings and development of the intervention are reported elsewhere [34]." *

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.

subitem not at all important □ □ □ □ □ essential
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

Your answer

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).

Subitem not at all important ○ ○ ○ ○ ○ essential

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

Your answer

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 ○ ○ ○ ○ ○ 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

Table 1
*Online Reminders:[42]

Remind providers: Develop reminder systems designed to help childcare providers to recall information and/or prompt them to implement the guidelines

Actor: Web-based program

Action: Fortnightly prompts to access the web-based program were displayed to services on their CCMS dashboard when: their current menu was not compliant with guidelines; insufficient information was entered into the program to calculate compliance; or their new menu cycle was due to be entered.

Targets: Menu planners, Supervisors

Temporality: Immediate commencement within intervention period

Dose: Fortnightly over the intervention period"
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  ○ ○ ○ ○ ○ 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.
Table 1
"Training and support to use the program."[38]

Conduct educational outreach visits: A trained person (health promotion officer with nutrition and dietetic qualifications) meet with childcare providers in their practice settings with the intent of changing their behaviour to implement the guideline.

Provide ongoing consultation: Provide ongoing consultation with one or more experts in the strategies used to support implementing the guidelines.

Centralise technical assistance: Develop and use a centralised system to deliver technical assistance focused on implementation issues.

Actor: Health promotion officer with nutrition and dietetic qualifications

Action: A face-to-face training session with a health promotion officer, with nutrition and dietetic qualifications and with extensive experience using the program, was provided to supervisors and menu planners. Training included information regarding the dietary guidelines for the sector, a demonstration of the web-based program and supporting resources, and an opportunity to answer any queries. Action planning and goal setting with staff was undertaken with the goal of facilitating integration of the program into existing roles and service procedures [44, 45].

Services received telephone support calls by a health promotion officer, tailored to their engagement with the program and menu compliance with guidelines.

Services were sent one newsletter via email and within the CCMS program, containing ideas to increase menu compliance, and tips for using the program.

Services without a current menu entered in the program and those who had not improved in menu compliance were offered an online booster training session [46].

Online support was also available from the technical and nutritional support teams of the CCMS provider via an online portal (help desk) already used by the services for all other IT queries.

Targets: Menu planners, Supervisors

Temporality: 3 hour face-to-face training session within 4 weeks of intervention commencement; 5-30 minute telephone support calls provided at 2 weeks, 8 weeks, 6 months, and 8 months; newsletter provided at 4 months; 15-60 minute online booster training sessions provided at 6 months.

Dose: Tailored to service needs – one-off face-to-face training session; up to 4 telephone support calls over 8 months; one-off newsletter; one-off online booster training session"

Table 1
"Additional resources (portable computer tablet):

Change equipment: Evaluate current configurations and adapt, as needed, the equipment (e.g. adding equipment) to best accommodate the targeted innovation

Actor: Health promotion officer with nutrition and dietetic qualifications

Action: Services were provided with a wifi-enabled computer tablet (Samsung Galaxy) to maximise integration of the online program into usual practice and provide the menu planner with portable access.

Targets: Menu planners, Supervisors

Temporality: Computer tablet provided at initial training session
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

"Data collection procedures and measures
Baseline data was conducted October 2016 - April 2017, with 12 month follow-up conducted October 2017 – March 2018.

Primary outcome: Mean number of food groups compliant with dietary guidelines.
As a summary indicator of childcare service menu compliance, the primary outcome was the mean number of food groups on the menu that were compliant with dietary guidelines for the sector [15], at 12 months follow-up. The majority of childcare services in NSW typically plan their menus in cycles of two – six weeks [18]. As such, at baseline, 3 and 12 month follow-ups, a dietitian or nutritionist blinded to service allocation randomly selected one week of each services’ current menu cycle for review to eliminate selection bias, using the random number function in Microsoft Excel 2010. Menus were assessed using best practice protocols [47] to calculate the number of serves of each food group that the menu provided per child, per day.

Dietary guidelines for the setting [15] recommend services provide the following serves of each of the following Australian Guide to Healthy Eating (AGHE) [14] food groups on a daily basis: (i) vegetables and legumes/bean (two serves); (ii) fruit (one serve); (iii) wholegrain cereals, foods and breads (two serves); (iv) lean meat and poultry, fish, eggs, tofu, seeds and legumes (3/4 serve); (v) milk, yoghurt, cheese and alternatives (one serve); and (vi) no ‘discretionary’ foods that are high in energy and low in nutrients (zero serves). A food group was only considered compliant when the recommended number of serves, and no discretionary foods, were provided for every child, every day over a one-week period. A menu was only considered compliant when the recommended number of serves of all food groups, and no discretionary foods, were provided for every child, every day over a one-week period.

Secondary outcomes:
i) Compliance with guidelines for all food groups: To identify absolute compliance with dietary guidelines, the proportion of services compliant for all of the six AGHE food groups was assessed via one-week menu review at baseline, 3 months and 12 months follow-up.

ii) Individual food group compliance with dietary guidelines: To identify variation in compliance with dietary guidelines for individual food groups, the proportion of services compliant with dietary guidelines for each of the six AGHE food groups individually was compared between the intervention and control group as assessed via one-week menu review at baseline, 3 months and 12 months follow-up. *

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 [16].

*subitem not at all important ☐ ☐ ☐ ☐ ☐ essential
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 (logs, logfile analysis, etc.). Use/adoption metrics are important process outcomes that should be reported in any eHealth trial.

subitem not at all important 〇 〇 〇 〇 〇 essential

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

Your answer

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).

subitem not at all important 〇 〇 〇 〇 〇 essential

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

Your answer

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

"(iii) Mean servings of individual food groups:
To identify any changes in the quantities or times an individual food group was provided on the menu, an additional exploratory outcome was included. This measure was not prospectively registered:
The mean number of serves for each of 5 AGHE food groups (vegetables, fruit, breads and cereals, meat and dairy) and the number of times discretionary foods were provided on the menu daily was compared between the intervention and control groups as assessed via one-week menu review (resulting in 5 days of data per service) at baseline, 3 months and 12 months follow-up."

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 ☐ ☐ ☐ ☐ ☐ ☐ essential

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

Your answer

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

NA

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

"Following the completion of baseline data collection, services were allocated to the intervention or control group in a 1:1 ratio, stratified by socioeconomic status (as determined by service postcode) [37] by an independent statistician using a random number function in Microsoft Excel 2010."

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

"Following the completion of baseline data collection, services were allocated to the intervention or control group in a 1:1 ratio, stratified by socioeconomic status (as determined by service postcode) [37] by an independent statistician using a random number function in Microsoft Excel 2010."

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  
"Following the completion of baseline data collection, services were allocated to the intervention or control group in a 1:1 ratio, stratified by socioeconomic status (as determined by service postcode) [37] by an independent statistician using a random number function in Microsoft Excel 2010."

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  
"All services in the sampling frame were posted an invitation letter and information statements about the study in random order, approximately two weeks prior to receiving a call from a research assistant to assess eligibility and obtain service consent to participate (August – December 2017)."

"Following the completion of baseline data collection, services were allocated to the intervention or control group in a 1:1 ratio, stratified by socioeconomic status (as determined by service postcode) [37] by an independent statistician using a random number function in Microsoft Excel 2010."

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).

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

Informed consent procedures (1a-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".

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  
"All outcome data assessors were blind to group allocation; however due to the nature of the trial childcare staff and health promotion officers delivering the intervention were aware of group allocation."

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

Your answer

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

NA

“Services randomly allocated to the control group did not receive access to the web-based menu planning program or other implementation support strategies.”

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

“All statistical analysis was undertaken using SAS 9.3 [49] by a statistician blinded to group allocation. All statistical analyses were two-tailed with an α value of 0.05. Service postcodes ranked in the top 50% of NSW according to the 2016 Socioeconomic Indices for Areas were classified as higher socioeconomic status [37]. Chi-square and t-test analyses were used to compare service and menu planner characteristics between intervention and control groups at baseline. The primary (mean number of food groups compliant with guidelines) and secondary menu outcomes (individual and all food group compliance with guidelines, and mean daily servings of individual food groups) were analysed with generalised linear mixed models, to account for repeated measures at the service level, as well as potential service level clustering effects for the mean daily servings of food groups analysis. The model included a random effect for service, as well as a group by time interaction to assess intervention effectiveness over the three time points.”

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]).

[ ] [ ] [ ] [ ] [ ] essential

[ ] [ ] [ ] [ ] [ ]
Does your paper address 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.

"For the primary and secondary outcomes, under an intention to treat framework, a complete case analysis was performed using all available data based on group allocation (without imputation), in addition to analysis using multiple imputation for missing data at follow-up undertaken using the MI procedure in SAS."

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.

NA

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)

X26-i) Comment on ethics committee approval

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

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.

Your answer

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 [5] for some items to be included in informed consent documents.

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

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.

Your answer

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)

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

Your answer

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.

"Twenty-seven services were randomised to intervention, and 27 services to the control. Two intervention services withdrew from the study prior to 12 months follow-up; one no longer prepared and provided meals, the other no longer wished to participate."

See Figure 1.

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.

"Twenty-seven services were randomised to intervention, and 27 services to the control. Two intervention services withdrew from the study prior to 12 months follow-up; one no longer prepared and provided meals, the other no longer wished to participate."

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.

subitem not at all important      o      o      o      o      o essential

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.

Your answer

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.

“All services in the sampling frame were posted an invitation letter and information statements about the study in random order, approximately two weeks prior to receiving a call from a research assistant to assess eligibility and obtain service consent to participate (August – December 2016).”

"Baseline data was conducted October 2016 - April 2017, with 12 month follow-up conducted October 2017 – March 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"

Subitem not at all important ○ ○ ○ ○ ○ essential

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.

Your answer

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.

NA

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.

See Table 2

“Services in the control arm had a significantly higher proportion of menu planners with a university qualification (19%) compared to services in the intervention (0%) (P<.02).”

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.

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.

See Table 2

"Services in the control arm had a significantly higher proportion of menu planners with a university qualification (19%) compared to services in the intervention (0%) (P=.02)."

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]", 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.

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.

See Figure 1 and Tables 2 - 6.

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).

subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 16-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.

Your answer

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

See Tables 3 and 4

"Primary outcome: Mean number of food groups compliant with dietary guidelines.

Whilst an increase in the mean number of food groups compliant with dietary guidelines from baseline to follow-up was found for both intervention and control services, no significant differences between the groups were found at 3 months (ES 0.52; 95% CI -0.35 to 1.39; P= .24) (Table 3) or 12 months follow-up (ES 0.26; 95% CI -0.61 to 1.14; P= .55).

Secondary outcomes

Compliance with guidelines for all food groups

At 3 months, only one service in the intervention arm was compliant with dietary guideline recommendations for all 6 food groups (Table 3). At 12 months follow-up, no services in either group were compliant with dietary guidelines for all 6 food groups. Statistical analysis was unable to be performed given inadequate values in all cells.

Individual food group compliance with dietary guidelines

An increase in the proportion of services compliant with individual food groups from baseline to follow-up was found for both intervention and control services, for the majority of food groups (4 out of 6), however no significant differences between groups were found at 3 or 12 months follow-up for any individual food group (Table 3).

No changes to the statistical significance of any outcomes were observed in the multiple imputation analyses, and as such these results are not reported."

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) [5] (report under item 5a).

subitem not at all important o o o o essential

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

Your answer

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

See Tables 3 and 4 for relative effect sizes.

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.

"Mean servings of individual food groups
At 3 months follow-up, menus from services in the intervention group provided significantly more mean daily servings of fruit, vegetables, dairy, meat, and reduced the number of times discretionary foods were provided compared to control (Table 4). At 12 months follow-up, menus from intervention services provided significantly more mean daily servings of fruit and significantly less discretionary foods compared to control service menus."

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-ii).

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

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.

Your answer

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.

NA

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].

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

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.

Your answer

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.

| subitem not at all important |   |   |   |   |   | essential |
|-----------------------------|---|---|---|---|---|-----------|
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.

Your answer

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).

subitem not at all important

|   |   |   |   |   |
|---|---|---|---|---|

essential

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 study is the first RCT measuring the effectiveness of a web-based menu planning program, linked to childcare management software systems, in improving childcare service compliance with dietary guidelines. The study found that, despite being considered acceptable by childcare service staff, the intervention did not significantly improve childcare service menu compliance with dietary guidelines, relative to control. However, significant increases in the servings of fruit, vegetables, dairy and meat on the menu, and a reduction in the times discretionary foods were provided were observed at 3 months. In addition, an increase in servings of fruit and reduction in the provision of discretionary foods at 12 months were found. Such findings suggest that while the web-based intervention did not improve menu compliance with guidelines, it increased the quantity of healthy foods, and decreased unhealthy foods provided on childcare service menus.”

“Among intervention services, there were high levels of acceptability, and variable levels of use of the web-based program (as evidenced by the large SDs and IQR in program use data).”

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

Highlight unanswered new questions, suggest future research.

subitem not at all important

|   |   |   |   |   |
|---|---|---|---|---|

essential

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.

Your answer
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.

Does your paper address subitem 20-i? *

"The study had notable strengths including the design (RCT), rigorous evaluation approaches, and inclusion of theory-driven and evidence-based intervention and implementation support strategies. Limitations, however were also present. Similar to previous trials within childcare services [58], the study yielded a moderate consent rate (47.4%). Whilst there were no significant differences in socioeconomic status for consenters and non-consenters, given the study was conducted within one state in Australia (NSW) with few indigenous services, it is unclear whether these findings are generalisable nationally or internationally. Furthermore, despite randomisation, services in the control arm had a significantly higher proportion of menu planners with a university qualification compared to intervention services. It is possible that this may account for the improvement in menu compliance observed in the control arm. While the menu planning program was linked to a CCMS platform to increase uptake and integration into daily routines, the program was not viewable on the main child enrolments page that is accessed on a daily basis by childcare service staff. Integrating the online the web-based menu planning program into the main CCMS platform of the software may reduce variability in service’s use of the program use. Finally, the outcome relating to servings of individual food groups provided on the menu was not prospectively registered, and should be interpreted with caution."

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

Does your paper address subitem 21-i? 

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.

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.

Your answer

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.

"The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN1261600974404)."

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.

"As previously described in a study protocol [34], "

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.

"This project is funded by the National Health and Medical Research Council project grant (APP1102943) and Cancer Council NSW (PG16-05). The NHMRC and CCNSW have played no role in the conduct of the trial. The content of this publication is the responsibility of the authors and do not reflect the views of NHMRC or CCNSW. Hunter New England Population Health and the University of Newcastle provided infrastructure funding. HealthyAustralia Ltd provided in-kind support. LW is a Hunter New England Clinical Research Fellow and is supported by Heart Foundation Future Leader Fellowship (Award No. 101175) and an NHMRC Career Development Fellowship (APP1128348). MF is a clinical research fellow funded by Hunter New England Population Health and the Health Research and Translation Centre, Partnerships, Innovation and Research, Hunter New England Local Health District. SY is a postdoctoral research fellow funded by the National Heart Foundation (Award No. 100547) and Australian Research Council (DE170100382)."
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.

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
Your answer

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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 *
2 hours

As a result of using this checklist, do you think your manuscript has improved? *
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☐ no
☐ Other:

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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
Your answer
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