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

***Obligatorio**

Your name *

First Last

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Title of your manuscript *

Provide the (draft) title of your manuscript.

Supporting the Medication Adherence of Older Mexican Adults Through External Cues
Provided With Ambient Displays: Feasibility Randomized 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.

Medication Ambient Display (MAD)

Evaluated Version (if any)

e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

Tu respuesta

Language(s) *

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

Spanish

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.

Tu respuesta

URL of an image/screenshot (optional)

Tu respuesta

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
- ☐ Otro:

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)"

Older adults

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

medication adherence

Secondary/other outcomes

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

Tu respuesta

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"
- ☐ Otro:

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%

☐ Otro:

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
- ☐ Otro:

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
- ☐ Otro:

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
- ☐ Otro:

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

☒ Otro: 14680

TITLE AND ABSTRACT**1a) TITLE: Identification as a randomized trial in the title****1a) Does your paper address CONSORT item 1a? ***

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

☒ yes

☐ Otro:

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.

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subitem not at all important

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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

This is the title: "Supporting the Medication Adherence of Older Mexican Adults Through External Cues Provided With Ambient Displays: Feasibility Randomized Controlled Trial". It indicates that it is as Ambient Display, which is defined in the paper's introduction using the appropriate references.

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”).

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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

There are no important co-interventions.

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

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subitem not at all important

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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

This is the title: Supporting the Medication Adherence of Older Mexican Adults

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)

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subitem not at all important

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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

"Background: On the basis of this, we propose to provide external cues to support the automatic retrieval of an intended action, that is, to take medicines. To reach this end, we developed the Medication Ambient Display (MAD), a system that unobtrusively presents relevant information (unless it requires the users' attention) and uses different abstract modalities to provide external cues that enable older adults to easily take their medications on time and be aware of their medication adherence.

Objective: This study aimed to assess the adoption and effect of external cues provided through ambient displays on medication adherence in older adults.

Methods: A total of 16 older adults, who took at least three medications and had mild cognitive impairment, participated in the study. We conducted a 12-week feasibility study in which we used a mixed-methods approach to collect qualitative and quantitative evidence. The study included baseline, intervention, and postintervention phases. Half of the participants were randomly allocated to the treatment group (n=8), and the other half was assigned to the control group (n=8). During the study phases, research assistants measured medication adherence weekly through the pill counting technique."

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)

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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

The intervention do not required the involvement of expert providers. The participants were 16 older adults as indicated in the METHODS section of the ABSTRACT.

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)

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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

.

The ABSTRACT's METHODS describe the following: "A total of 16 older adults, who took at least three medications and had mild cognitive impairment, participated in the study. We conducted a 12-week feasibility study in which we used a mixed-methods approach to collect qualitative and quantitative evidence. The study included baseline, intervention, and postintervention phases. Half of the participants were randomly allocated to the treatment group (n=8), and the other half was assigned to the control group (n=8). During the study phases, research assistants measured medication adherence weekly through the pill counting technique."

In the body text, there is additional information about how participants were recruited and the instruments used to assess the outcomes.

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)

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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

"Results: The treatment group improved their adherence behavior from 80.9% at baseline to 95.97% using the MAD in the intervention phase. This decreased to 76.71% in the postintervention phase when the MAD was no longer being used. Using a one-way repeated measures analysis of variance and a post hoc analysis using the Tukey honestly significant difference test, we identified a significant statistical difference between the preintervention and intervention phases ($P=.02$) and between the intervention and postintervention phases ($P=.002$). In addition, the medication adherence rate of the treatment group (95.97%) was greater than that of the control group (88.18%) during the intervention phase. Our qualitative results showed that the most useful cues were the auditory reminders, followed by the stylized representations of medication adherence. We also found that the MAD's external cues not only improved older adults' medication adherence but also mediated family caregivers' involvement."

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)

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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

"Results:..... In addition, the medication adherence rate of the treatment group (95.97%) was greater than that of the control group (88.18%) during the intervention phase.

Conclusions: The findings of this study demonstrate that using ambient modalities for implementing external cues is useful for drawing the attention of older adults to remind them to take medications and to provide immediate awareness on adherence behavior."

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)

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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

"Therefore, we propose to support external cues through a tablet-based ambient display designed to increase the retrieval process of the planned action (ie, taking medications) and to provide awareness of adherence behavior [11,12]. To reach this end, we designed the Medication Ambient Display (MAD) [12,13].

An ambient display unobtrusively presents relevant information unless it requires the users' attention [14]. In addition, users can easily monitor the display to obtain the desired information because it uses abstract modalities to represent information, such as pictures, sounds, and movement [14]. Thus, we used different abstract modalities to provide external cues that enable older adults to easily obtain relevant information to take their medications on time and be aware of their medication adherence.

.....

In contrast to the previously mentioned works, our technological approach uses ambient modalities to provide external cues that aim to increase the retrieval process of the planned action and to provide daily and immediate awareness about how medication regimens are followed during the day. We assessed the effect of our approach by using objective medication adherence measures; moreover, we obtained qualitative findings that help us understand the adoption of the MAD. For this end, we provided seniors with the MAD to support the medication treatments prescribed by their physicians and the timetables that the seniors themselves proposed to follow."

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.

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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

"....."

In contrast to the previously mentioned works, our technological approach uses ambient modalities to provide external cues that aim to increase the retrieval process of the planned action and to provide daily and immediate awareness about how medication regimens are followed during the day....."

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

"Objectives

Our study aimed to address the following research questions (RQ):

RQ1: What is the effect of the external cues provided by the MAD on older adults' medication adherence?

RQ2: How do the MAD design features promote its adoption?"`

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

"Baseline data were collected during weeks 6 to 10 on medication adherence by using the pill counting technique"....."We conducted a session with the research assistants, who made a random and blind allocation of the participants to the treatment group (TG) and the control group (CG)...."

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

"Baseline data were collected during weeks 6 to 10 on medication adherence by using the pill counting technique. We noticed that participants accumulated containers with the same medications. Under those circumstances, we provided seniors with a basket to arrange the medications that should be taken each week (see Figure 2), which facilitated data collection for measuring the Dosage_pill adherence outcome."

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].

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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

No.

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

"To be eligible, older adults had to meet the following criteria: be older than 60 years, take at least three medications prescribed by a physician (ie, polypharmacy), have mild cognitive impairment, report medication-forgetting events, and live with a relative who could provide us with information on the assistance required by the study participant to take their medications. The exclusion criteria were as follows: being unable to self-administer medications due to a functionality problem or severe cognitive impairment, and not taking pill-based medications (it may be difficult to assess adherence otherwise). To participate in the study, it was not a requirement that older adults have experience in the use of the internet or mobile devices."

4a-i) Computer / Internet literacy

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

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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

"....To participate in the study, it was not a requirement that older adults have experience in the use of the internet or mobile devices."

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.

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Does your paper address subitem 4a-ii? *

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

"The study was conducted in Mexicali, Mexico. Ten students from the Faculty of Nursing at the Universidad Autónoma de Baja California participated as research assistants. These students were enrolled in a social service program at the Community Center of the University (known as the UNICOM), which aims to provide seniors with occupational therapy and provide some health care assistance. The UNICOM is strategically located in a neighborhood where aging inhabitants predominate. For recruiting participants, research assistants contacted older adults in the vicinity of the UNICOM and administered a set of instruments as summarized in Table 1. First, the Spanish version of the 10-item Short Portable Mental Status Questionnaire was administered..... In addition, relatives of older adults were interviewed to identify their role in helping older adults follow their medication routine. Older adults who met the eligibility criteria and expressed their interest to participate were enrolled in the study. The recruitment procedure lasted approximately 5 weeks."

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.

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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

"Older adults who met the eligibility criteria and expressed their interest to participate were enrolled in the study.....We obtained informed written consent from all individual participants."

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

"The study was conducted in Mexicali, Mexico. Ten students from the Faculty of Nursing at the Universidad Autónoma de Baja California participated as research assistants. These students were enrolled in a social service program at the Community Center of the University (known as the UNICOM), which aims to provide seniors with occupational therapy and provide some health care assistance. The UNICOM is strategically located in a neighborhood where aging inhabitants predominate.....Once the participants were recruited, we realized that they were primarily of low socioeconomic status and affiliated with the Mexican Institute of Social Security (IMSS), the largest medical institution in Mexico. Periodically (monthly or bimonthly), they attended an IMSS clinic for follow-up consultation and to retrieve an updated prescription to get their medications from the clinic's pharmacy. The lack of adequate health care and pharmaceutical policies to rationally manage medications and monitor the treatment of patients increases the vulnerability of Mexican seniors to medication errors [31], a situation that is also faced in other countries [32,33]."

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.

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subitem not at all important

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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

We did not use online questionnaires, but we used questionnaires for the self-assessment of medication adherence as stated in the paper: "...the 8-item Medication Adherence Questionnaire (MAQ-8) scale was used to identify nonadherent seniors through 8 questions [27]..."

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)

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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

Participants were informed by the research assistants that this was a project of the Autonomous University of Baja California.

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).

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subitem not at all important

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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

"Conflicts of Interest
None declared".

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.

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subitem not at all important

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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

"Design and Implementation of the Medication Ambient Display

For medical information systems to be more specific to the needs of users, an iterative approach must be followed, which consists of different usability studies [34]. In this sense, our previous work included usability studies that helped us inform the design of the MAD. They included (1) a usability inspection in which experts (usability engineers and geriatricians) determined how the MAD conformed to usability design principles for ambient displays [11] and (2) a field evaluation to identify technical and usability problems that we addressed without altering the conceptual design of the MAD [12,13]. In this paper, we present the trial study that we conducted to evaluate the effect of the MAD on measures of adherence to medication and its possible adoption....."

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).

1 2 3 4 5

subitem not at all important

essential

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 intervention did not have major changes during the evaluation process.

5-iv) Quality assurance methods

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

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subitem not at all important

essential

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

We do not follow any specific quality assurance method.

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.

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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

We provided screen-shots of the system's user interfaces, and the system's functionality is explained based on how its interfaces enable users to access their medication information.

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.

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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

We published in this paper the screen shots of the system's user interfaces.

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).

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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

We provided participants with a Tablet PC which was withdrawn at the end of the study as stated in the paper: "We implemented the MAD for Android tablets to be placed as portrait frames in the older adults' homes.....The ethics review board of Faculty of Nursing approved the study protocol once we proposed how to address their suggestions on how to handle the withdrawal of the technology at the study end. We agreed to provide the participants of the TG with an adequate financial incentive that would allow them (if desired) to obtain a PC tablet similar to the one used during the study. Every week, participants received an economic incentive, approximately US \$7 if they were in the CG and US \$14 if they were in the TG. We obtained informed written consent from all individual participants."

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].

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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

This item is addressed in the Introduction and Methods sections.

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.

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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

Table 2 describes the outcome variables and methods used to collect data to address research question.

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).

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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

Research assistants conducted the data collection during as stated in the paper: "Ten students from the Faculty of Nursing at the Universidad Autónoma de Baja California participated as research assistants. These students were enrolled in a social service program at the Community Center of the University (known as the UNICOM), which aims to provide seniors with occupational therapy and provide some health care assistance...."

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).

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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

We did not provided any reminder to use the system.

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).

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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

"On the first day of this phase, research assistants visited older adults in the TG to introduce the MAD in the presence of caregivers by using the spaced retrieval approach, that is, teach, ask, wait, ask again, wait, and ask again [35]....."

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

Table 2 Describes the outcome variables and methods used to collect data to assess them. We explain the methods used to Analyze the outcomes in the Data Analysis section: "We used Student t tests and chi-square tests to measure the statistical difference in age, the number of prescribed medicines, and self-reported medication adherence between the TG and the CG. A one-way repeated measure analysis of variance (ANOVA), dependent t tests, and independent t tests were used to find significant differences in medication adherence between the study phases and between the TG and the CG. The McNemar test was used to verify differences within the TG between the self-reported medication adherence in the recruitment and intervention phases. To determine whether any of the differences between the means estimated are statistically significant, we compared the P value with a significance level set to .05 [35]."

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].

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subitem not at all important						essential

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

We do not use online questionnaires.

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

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

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subitem not at all important						essential

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

"During the intervention phase, we also collected qualitative evidence about the system's adoption, which enabled us to address RQ2. We interviewed the older adults in the TG regarding the system's functionalities that they perceived as most useful, less useful, and the difficulties faced while using it. At the end of the post-intervention stage, we interviewed participants to obtain their perceptions of how withdrawal from the MAD impacted their medication adherence. In addition, those caregivers who were at home during our visits were interviewed to obtain information on their involvement in the seniors' medication activities. Our questions centered on the specific activities associated with the older adult's medication regimen that caregivers were involved in and how they knew if the older adult took his or her pills in a given week. These semistructured interviews were administered by the first 3 authors of this paper.....For the qualitative analysis, we transcribed the collected data from their original Spanish version, that is, audio, handwritten notes, and photographs taken during the interviews. Individual quotes were translated into English for use in this paper. We followed the thematic analysis approach, which consists of generating initial codes from the data, searching for potential themes, contrasting the identified themes with the data, and iteratively refining them [36]."

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).

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subitem not at all important

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Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

"During the intervention phase, we also collected qualitative evidence about the system's adoption, which enabled us to address RQ2. We interviewed the older adults in the TG regarding the system's functionalities that they perceived as most useful, less useful, and the difficulties faced while using it. At the end of the post-intervention stage, we interviewed participants to obtain their perceptions of how withdrawal from the MAD impacted their medication adherence. In addition, those caregivers who were at home during our visits were interviewed to obtain information on their involvement in the seniors' medication activities."

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

"Baseline data were collected during weeks 6 to 10 on medication adherence by using the pill counting technique. We noticed that participants accumulated containers with the same medications. Under those circumstances, we provided seniors with a basket to arrange the medications that should be taken each week (see Figure 2), which facilitated data collection for measuring the Dosagepill adherence outcome (see Table 2)."

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.

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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

As it is a feasibility study, we determined the sample size based on the resources that we had for providing them with Tablets PC and economic incentives for enabling to access data.

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

We do not used and interim analysis and stopping guidelines.

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 conducted a session with the research assistants, who made a random and blind allocation of the participants to the treatment group (TG) and the control group (CG)."

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

"We conducted a session with the research assistants, who made a random and blind allocation of the participants to the treatment group (TG) and the control group (CG)."

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

"We conducted a session with the research assistants, who made a random and blind allocation of the participants to the treatment group (TG) and the control group (CG)." Ten research assistants participated in this session. Each of the assistants blindly selected a participant number from a tray. Then they placed the selected number in one of the other two trays corresponding to TG and CG.

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

"We conducted a session with the research assistants, who made a random and blind allocation of the participants to the treatment group (TG) and the control group (CG)."

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).

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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

We did not address this item.

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

Participants were informed about the interventions to use since they were recruited and signed the informed consent to accept using any of the interventions.

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

It is not relevant.

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

"We used Student t tests and chi-square tests to measure the statistical difference in age, the number of prescribed medicines, and self-reported medication adherence between the TG and the CG. A one-way repeated measure analysis of variance (ANOVA), dependent t tests, and independent t tests were used to find significant differences in medication adherence between the study phases and between the TG and the CG. The McNemar test was used to verify differences within the TG between the self-reported medication adherence in the recruitment and intervention phases. To determine whether any of the differences between the means estimated are statistically significant, we compared the P value with a significance level set to .05 [35]."

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]).

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subitem not at all important

essential

Does your paper address subitem 12a-i? *

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

"They identified 42 potential participants; 20 of them met the eligibility criteria and were enrolled in the study. However, only 16 completed the study. The analysis of baseline data presented in Table 3 indicated that the TG and the CG had no significant differences in age ($P=.21$), number of medicines taken ($P=.33$), self-reported medication adherence ($P=.59$), education in years ($P=.35$), gender ($P=.25$), relationship with caregiver ($P=.57$), and dosage outcome ($P=.77$). For the data analysis, we used the data collected from the 16 participants that completed the study.

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

We did not conducted additional analysis.

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

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subitem not at all important

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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

"The ethics review board of Faculty of Nursing approved the study protocol once we proposed how to address their suggestions on how to handle the withdrawal of the technology at the study end. We agreed to provide the participants of the TG with an adequate financial incentive that would allow them (if desired) to obtain a PC tablet similar to the one used during the 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.

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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

"We obtained informed written consent from all individual participants."

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)

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subitem not at all important

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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

"On the first day of this phase, research assistants visited older adults in the TG to introduce the MAD in the presence of caregivers by using the spaced retrieval approach, that is, teach, ask, wait, ask again, wait, and ask again [35]. This approach has been used to support the encoding, retention, and retrieval processes involved in interventions designed to assist medication taking [35]. Thus, we explained to participants how to carry out medication taking using the system. Afterward, we asked them to recall the system features we had just presented and assisted them as necessary. To do this, we activated each of the system's functionalities and asked participants to use them (eg, interpreting a reminder, registering a medication, and consulting and interpreting their medication compliance). Then, we waited for 1 min and asked them to recall the system's functionalities again. We asked them again 15 min later and repeated it once again."

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

"The research assistants contacted approximately 100 older adults to participate in the study (see Figure 8). They identified 42 potential participants; 20 of them met the eligibility criteria and were enrolled in the study. However, only 16 completed the study..... On the first day of this phase, research assistants visited older adults in the TG to introduce the MAD in the presence of caregivers.....The TG improved their adherence behavior (dosage), increasing from 80.9% in the preintervention phase to 95.97% in the intervention phase. However, it decreased to 76.71% in the postintervention phase. Using a one-way repeated measures ANOVA, we compared the effect of the MAD in the TG during the 3 phases.....The medication adherence rate of the TG (mean 95.97% [SD 6.08%]) was higher than that of the CG (mean 88.18% [SD 13.06%]) during the intervention phase. ."

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

Figure 8 shows a flow diagram of the participants' progress through the study phases.

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

See figure of Appendix 1. ".....Multimedia Appendix 1 shows that participant P2 has adherence rates higher than 100% according to both techniques. Similarly, overmedication could be present in the baseline data, which impacted the high medication rates registered for some older adults (eg, participants P7 and P8). However, our results show that the introduction of the MAD's external cues to the TG resulted in significant improvements in the average rates of dosage outcomes, which addresses RQ1."

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

"The evaluation of the MAD was designed as a small trial study. This section presents the study timeline, the activities conducted, and the instruments used to collect data (see Figure 1)."

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”

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subitem not at all important

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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

The item is not applicable/relevant since there were no critical “secular events”.

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

It is not applicable.

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 3.

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.

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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 3 which shows demographics such as gender, education and age. We also reported the following: "Once the participants were recruited, we realized that they were primarily of low socioeconomic status and affiliated with the Mexican Institute of Social Security (IMSS), the largest medical institution in Mexico.....The analysis of baseline data presented in Table 3 indicated that the TG and the CG had no significant differences in age ($P=.21$), number of medicines taken ($P=.33$), self-reported medication adherence ($P=.59$), education in years ($P=.35$), gender ($P=.25$), relationship with caregiver ($P=.57$), and dosage outcome ($P=.77$)."

16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

16-i) Report multiple “denominators” and provide definitions

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

1 2 3 4 5

subitem not at all important

essential

Does your paper address subitem 16-i? *

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

"All older adults, except participant P4, reported that they did not consult the detailed information on their medication adherence, but they verified if the parakeet grew after registering the medication as taken.....Participant P6 was the only participant who, during the interviews, admitted forgetting to take her medication because as a consequence... "

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

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

Not applicable.

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

"Dosagepill (Treatment Group)

The TG improved their adherence behavior (dosage), increasing from 80.9% in the preintervention phase to 95.97% in the intervention phase. However, it decreased to 76.71% in the postintervention phase. Using a one-way repeated measures ANOVA, we compared the effect of the MAD in the TG during the 3 phases. It showed a significant statistical difference between at least two of the phases ($F_{2,14}=6.59$; $P=.0096$). With a post hoc analysis using the Tukey honestly significant difference test, we identified a statistical difference between the preintervention and intervention phases ($P=.02$) and between the intervention and postintervention phases ($P=.002$); Cohen effect size values ($d=1.35$ and $d=1.72$, respectively) suggest a high practical significance in both cases. In addition, there was no statistical difference between the preintervention and the postintervention phases ($P=.73$). Therefore, these results are evidence that the external cues of the MAD contributed to improving the medication intake behaviors of older adults.

Dosagepill (Control Group)

The CG increased their medication adherence between the preintervention (mean 79.87% [SD 20.49%]) and intervention phases (mean 88.18% [SD 20.49%]). However, according to a paired-samples t test, there was not a significant difference ($t_7=1.15$; $P=.14$). The Cohen effect size value ($d=0.41$) suggests a medium practical significance. We attributed this increase in dosage rates to the medication monitoring conducted weekly by the research assistants and to the basket provided to organize the pills containers."

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).

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subitem not at all important

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

In Table 2, it is indicated the following: " [Timely outcome] It indicates whether the medication was taken 30 min before or after the time expected to take the medication. This is the number of medication episodes registered in the time window during a period divided by the number of episodes registered as taken for that period"

In the text, it is explained:We obtained 2224 medication episodes registered in the MAD's log, of which 93.17% (2072/2224) were registered as taken on time, and 88.35% (1830/2224) of these timely episodes were taken after the MAD reminders. As illustrated in Table 4, most of the participants showed a high reminder dependency rate. These results are evidence that the MAD reminders resulted in medication-taking behaviors consistently."

17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT subitem 17b? *

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

No applicable.

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

No applicable.

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).

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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

Not applicable.

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

See the Limitations sections: "Although using our technology did not introduce any risk, it might have supported inappropriate medication routines adopted by older adults to overcome some of the barriers imposed by the setting. We recognize the importance of conducting a contextual study before conducting a technology evaluation. The contextual study should be designed in collaboration with clinical or nursing specialists to reduce the complexity of older adults' medication regimens and the risks associated with the way they manage medications. "

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].

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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

"Although using our technology did not introduce any risk, it might have supported inappropriate medication routines adopted by older adults to overcome some of the barriers imposed by the setting. We recognize the importance of conducting a contextual study before conducting a technology evaluation. The contextual study should be designed in collaboration with clinical or nursing specialists to reduce the complexity of older adults' medication regimens and the risks associated with the way they manage medications. "

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.

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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

"...we obtained qualitative findings that explained the adoption of the MAD from the perspectives of both seniors and their relatives..."

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).

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	☐	☐	☐	☐	☒	
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

"System Adoption (Research Question 2)

The collected qualitative evidence helps us to address RQ2 and to complement the quantitative results. We analyzed the data collected from the interviews administered to participants P1 to P8 of the TG....."

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

Highlight unanswered new questions, suggest future research.

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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

".....For future work, we plan to conduct studies to assess the feasibility of external ambient cues to support the seamless integration of medication regimens into the daily routines of the elderly....."

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.

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subitem not at all important

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

See Limitations section: "Economic Incentive for Participating

The use of financial incentives has been questioned because they may provide inducements to participate in a study for financial purposes only, and vulnerable populations are prone to be enticed by the financial reward and be more willing to accept any study risks [38]. In our opinion, offering an incentive facilitated recruitment of participants and allowed us to access their data, which would otherwise be considered an obtrusive task. For instance, 2 participants explicitly asked for the weekly economic incentive to allow the research assistants to collect data; another participant questioned the incentive since she considered it was unnecessary for being part of the study. Although we are not able to conclude on how the incentive impacted the adoption of the technology, our findings indicate that the MAD was accepted not only by older adults but also by their family caregivers.

Setting Characteristics

We observed that some participants faced problems in managing their medications, such as accumulating medications, confusing medications because they look alike, and tending to give medications to others, which may not be an appropriate practice. The design of our study was limited in that the MAD system was personalized according to the prescribed medication regimens and timetables that the participants followed."

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

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subitem not at all important

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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

".... Finally, we are not able to state that our results are generalizable to the whole Mexican elderly population. This is because participants were primarily from a low-income socioeconomic stratum; therefore, exploring this technology among high-income elders who have access to private health care services might produce different findings....."

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.

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subitem not at all important

essential

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

This item are addressed in the Introduction and Discussion sections.

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

No trial registry of this feasibility study.

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

Not applicable.

25) Sources of funding and other support (such as supply of drugs), role of funders**Does your paper address CONSORT subitem 25? ***

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

"...The National Council of Science and Technology (CONACyT) in Mexico and the Autonomous University of Baja California supported this work under grant numbers 153863 and 1914...The authors want to thank CONACyT for the scholarships provided to the first and seventh authors."

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.

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☐ ☐ ☐ ☒ ☐

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

"Ten students from the Faculty of Nursing at the Universidad Autónoma de Baja California participated as research assistants. These students were enrolled in a social service program at the Community Center of the University (known as the UNICOM), which aims to provide seniors with occupational therapy and provide some health care assistance....

During the study phases, research assistants measured medication adherence weekly through the pill counting technique....."

About the CONSORT EHEALTH checklist

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?

Tu respuesta

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

3 hours

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

☐ yes

☒ no

☐ Otro:

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

☐ Otro:

Any other comments or questions on CONSORT EHEALTH

Tu respuesta

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