Author’s response to reviews

Title: Can an App Supporting Psoriasis Patients Improve Adherence to Topical Treatment? A single-blind randomized controlled trial

Authors:

Mathias Tiedemann Svendsen (mathias.tiedemann.svendsen@rsyd.dk)
Flemming Andersen (Flemming.Andersen1@rsyd.dk)
Kirsten Hammond Andersen (kha@dermatologicalinvestigations.org)
Klaus Ejner Andersen (klaus@maxa.dk)

Version: 2 Date: 06 Jan 2018

Author’s response to reviews:

RESPONSE TO REVIEWER

I Thank the reviewer for the valuable comments. As corresponding author, I have addressed the comments from the reviewer. Changes to the manuscript have been approved by all my co-authors. Below my point-to-point answers with a reference to the revisions based on the comments from the reviewer.

The line numbers refer to the clean version of the uploaded manuscript unless other is stated.

Since BMC Dermatology is an European Journal, we have added a “Cal/BD cutaneous foam” throughout the whole manuscript, to reflect approvals by EMA for the product Enstilar®.

1). - please clarify in the title/abstract what you mean by 'a designed patient-centered intervention.....'

ANSWER:

Years back our research group aimed for designing an adherence-improving intervention and used the title “designed intervention” in study protocol materials. We ended up testing an app.

The sentence “a designed patient-centered intervention” is redundant, since all apps are designed.

This has led to changes in the title
1. 3-4: “A Designed Patient-Centered Intervention to Improve Medical Adherence in Topical treatment of psoriasis: A single-blind randomized controlled trial”

(manuscript in track changes mode uploaded as supplementary file)

to

1. 3-4: “Can an App Supporting Psoriasis Patients Improve Adherence to Topical Treatment? A single-blind randomized controlled trial”

This has led to changes in the abstract from

1. 33-34: To the best of our knowledge, this is the first protocol for an RCT to test an app designed to improve adherence to a topical antipsoriatic drug”

(manuscript in track changes mode uploaded as supplementary file)

to

1. 45-46: To the best of our knowledge, this is the first protocol for an RCT to test if an app supporting psoriasis patients can improve adherence to a topical antipsoriatic drug.

2). - how the EM cap measures treatment session (cap being taken off, or similar)

ANSWER:

Additional sentences describing how the EM cap measures number of treatment sessions have been inserted:

1. 35-36: “The EM contains a chip registering the amount of foam, day and time the patient use the foam dispenser.”

and

1. 122-123: “EM (that contains a chip registering the amount of foam, day and time the patient use the foam dispenser)”

3). - please clarify the randomization methods - block randomization stratified by age and gender (or also socioeconomic status, illness duration etc; see page 13 and page 19)

ANSWER:

An additional sentence describing the block randomization has been inserted:

1. 287-289: “Parallel-assigned block randomization (1:1) will be done in eight blocks stratified by age and gender. The randomization code will be stored with the data manager and the
randomization list will be made with a computer-generated sequence in the randomization tool REDCap.”

4.1 please clarify your null hypothesis. I assume that both groups receive the medication with the EM unit (Otherwise the difference in treatment sessions between groups could not be measured). If I understood correctly, you then actually measure the ‘adherence in intervention group (EM + App) versus non-intervention group (EM no App).

ANSWER:

The null hypothesis has been clarified with a separate subheading:

from

l. 159-164:” Null hypothesis: For participants: There is no difference in medical adherence to a topical Cal/BD product among the intervention group using the app with the EM versus the non-intervention group. Thesis: The purpose of the trial is to reject the null hypothesis above.”

(manuscript in track changes mode uploaded as supplementary file)

to

l. 146-151: Null hypothesis

“Null hypothesis

There is no difference in medical adherence to a topical Cal/BD product among psoriasis patients using the app (the intervention group) versus those without access to the app (the non-intervention group).

Thesis: The purpose of the trial is to test the null hypothesis.”

4.2 In this case it would be very important to add information about the intervention, which is the APP (not the EM unit). Please add a section on the App:

ANSWER:

A separate section on the app is inserted

l. 115-129:

“Intervention: detailed description of the app

The EM unit and app are designed and owned by LEO® Pharma (LEO®). The app design is based on results from systematic literature reviews on adherence to topical antipsoriatic treatments [7, 8] with the goal of improving adherence rates. The app focuses on reducing
forgetfullness, and at the same time incorporates functionalities that motivate (i.e. nudge) patients to use their medication [28] and thereby reduce obtrusive behaviors towards medication [29].

The patient-support app, combined with the EM unit, has three functions: 1) to provide patients with a measurement of their consumption of medicine by synchronizing to the EM (that contains a chip registering the amount of foam, day and time the patient use the foam dispenser), 2) to measure the severity of their psoriasis by having the patients state their symptoms in a diary (optional) and 3) to support patients in their treatment and refills through compulsory reminder messages that once daily pop up on the smartphone screen with a short alert sound and through use of optional educational and motivational text materials in the app.

Written information on the intervention, including photos where layout on the smartphone touch screen is displaced, is provided for participants at the baseline visit (additional file 5, https://Goo.gl/sv4y76).”

4.3 What kind of messages are send, how often, does it pop up on the screen?

ANSWER:

Detailed description is inserted

l. 33-34: “A 28-day adherence-supporting app providing compulsory daily treatment reminders that pop up on the smartphone screen with a short alert sound”

and

l. 124-126: “(…) to support patients in their treatment and refills through compulsory reminder messages that once daily pop up on the smartphone screen with a short alert sound”

4.4. Are pictures being used?

ANSWER:

No clinical photos are being used. We have chosen not to describe what is not in the app.

4.5. Is the information send based on a theory or similar?

ANSWER:

The compulsory information send (the daily treatment reminders) is based on forgetfulness as a determinant of non-adherence reported in the international literature. Additionally some components in the app is incorporated with the purpose of motivating the patients to adhere to the treatment based on theories of “nudging”.

Additional sentences inserted
1. 92-93. “The literature described 34 multifactorial determinants of medical non-adherence [10-12, 14, 15, 17, 18], where forgetfullness was the most frequently reported determinant [11, 15, 18].

and

1. 115-120:” Intervention: detailed description of the app

The EM unit and app are designed and owned by LEO® Pharma (LEO®). The app design is based on results from systematic literature reviews on adherence to topical antipsoriatic treatments [7, 8] with the goal of improving adherence rates. The app focuses on reducing forgetfullness, and at the same time incorporates functionalities that motivate (i.e. nudge) patients to use their medication [28] and thereby reduce obtrusive behaviors towards medication [29].”

4.6. Perhaps the TIDIER checklist would be useful here
http://www.bmj.com/content/348/bmj.g1687

ANSWER:

The 12-point TIDIER checklist is inserted below with references to line numbers (l.) in the revised manuscript and Supplementary Material (links to uploaded materials are provided throughout the revised manuscript).

Brief name
1. Provide a name or a phrase that describes the intervention

ANSWER:

1. 112-113

and

(additional file 5, https://Goo.gl/sv4y76)

Why
2. Describe any rationale, theory, or goal of the elements essential to the intervention

ANSWER:

1. 92-94

and
3. Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL)

ANSWER:

(additional file 5, https://Goo.gl/sv4y76)

4. Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities

ANSWER:

5. For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given

ANSWER:

and

How

6. Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention or whether it was provided individually or in a group

ANSWER:

Where

7. Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features
When and How Much

8. Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose

ANSWER:

Ibid.

Tailoring

9. If the intervention was planned to be personalized, titrated or adapted, then describe what, why, when, and how

ANSWER:

NA (Not Applicable)

Modifications

10. If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)

ANSWER:

NA

How well

11. Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them

ANSWER:

NA

12. Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned

ANSWER:

NA
Please read the following information and revise your manuscript as necessary. If your manuscript does not adhere to our editorial requirements, this may cause a delay while this is addressed. Failure to adhere to our policies may result in rejection of your manuscript.

I. In accordance with BioMed Central editorial policies and formatting guidelines, all manuscript submissions to BMC Dermatology must contain a Declarations section which includes the mandatory sub-sections listed below. Please refer to the journal's Submission Guidelines web page for information regarding the criteria for each sub-section (https://bmcdermatol.biomedcentral.com/).

Where a mandatory Declarations section is not relevant to your study design or article type, please write "Not applicable" in these sections.

ANSWER:

Point-to-point answers on where information can be found in the study protocol manuscript are provided below.

I. For the 'Availability of data and materials' section (http://www.biomedcentral.com/submissions/editorial-policies#availability+of+data+and+materials), please provide information about where the data supporting your findings can be found. We encourage authors to deposit their datasets in publicly available repositories (where available and appropriate), or to be presented within the manuscript and/or additional supporting files. Please note that identifying/confidential patient data should not be shared. Authors who do not wish to share their data must confirm this under this sub-heading and also provide their reasons. For further guidance on how to format this section, please refer to BioMed Central's editorial policies page (see links below).

ANSWER:

1. 518-523.

Declarations

- I.II. Ethics approval and consent to participate

(Ethical approval and consent: http://www.biomedcentral.com/about/editorialpolicies#Ethics)

ANSWER:

1. 554-558.

- I.III. Consent to publish
ANSWER:
1. 551-552.

- I.IV. Availability of data and materials

ANSWER:
1. 518-523.

- I.V. Competing interests

ANSWER:
1. 547-549

- I.VI. Funding

ANSWER:
1. 503-516.

- I.VII. Authors' Contributions

ANSWER:
1. 525-545.

- I.VIII. Acknowledgements

ANSWER:
1. 496-500.