RESEARCH CONSENT FORM

Nurse-led medication self-management intervention in the improvement of medication adherence in adult patients with multi-morbidity: A Feasibility Randomized controlled trial

Dr. Badriya Lenjawi

Date-2 Nov 2022

NCT- Not available

1. Title of research

Nurse-led medication self-management intervention in the improvement of medication adherence in adult patients with multimorbidity: a feasibility randomized controlled trial

2. Principal Investigator

Dr Badriya Abdulla Al Lenjawi

3. Why are we inviting you to join this research?

The investigator and colleagues at Hamad Medical Corporation (HMC) are conducting this research.

We are inviting you to join because you are having at least one medication prescribed for a chronic condition over at least the 3 months prior to inclusion in the study

4. What should you know about this research?

- We will explain the research to you
- Whether or not you join is your decision (you can accept or refuse no matter who is inviting you to participate)
- Please feel free to ask questions or mention concerns before deciding, or during or after the research
- You can say yes but change your mind later
- We will not hold your decision against you

5. Who can you talk to?

If you have questions or concerns, or if you think the research has hurt you, talk to the research team at:
Dr Badriya Abdulla Al Lenjawi, blenjawi@hamad.qa, 44397804
If you have questions about your rights as a volunteer, or you want to talk to someone outside the research team, please contact:

- HMC-IRB Office at 4025 6410 (from Sunday to Thursday between 7:00am-3:00pm) or email at irb@hamad.qa

6. Why are we doing the research?

The current study aims to implement evidence-based, theoretical and nurse-led drug self-management interventions in adult patients with multimorbidity and examine its effects in community settings. The study results may lead to improve the compliance to medication in patients with chronic diseases.

7. How long will the research take?

We think that you will be in the research for a maximum of three months. The patients in intervention group will have three face to phase education session and two session through telephone. All Participants will be assessed at baseline , in the 7th week post-intervention ,and at 3-month post-intervention.

8. How many people will take part?

We plan to study 100 patients who are visiting the OPDs of NCCCR , Hamad Medical Corporation.

9. What happens if you take part?

If you agree to join, we will ask you to do the following:
Research subjects will be recruited by CNS at the OPD of NCCCR. Based on the inclusion and exclusion criteria CNS will approach you to take part in the study. One-week time will be given you to decide to take part in the study. You will be "randomized" into one of the two study groups.
Primary and secondary study outcomes of better medication adherence, medication self-management capacity and treatment experiences, will be collected for the intervention group and control group at first of the enrollment of the study, in the 7th week post-intervention, and at 3-month post-intervention.
Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researchers choose which group you will be in. You will have a 50% chance of being place in a specific group.
If you are belonging to the intervention group, you will be invited to attend a 40-minute face to face education session for three weeks and two weekly sessions over the telephone for 20 minutes. If you are in control group, still you will receive the standard care from the health care provider.

For collecting the information regarding medication knowledge using Perceived Knowledge in Medication Use Questionnaire, Medication beliefs using Beliefs about Medication Questionnaire BMQ, Medication self-efficacy Using The Self-Efficacy for Appropriate Medication Use Scale (SEAMS), treatment burden using Treatment Burden Questionnaire (MTBQ) Questionnaire.

10. Could the research be bad for you?

There will not be any risk for you in participating in this study.
However, if you are belonging to the intervention group you may visit to NCCCR OPD for at least three times to attend the weekly intervention session and you two weekly sessions over the telephone for 20 minutes

11. Could the research be good for you?

We cannot promise any benefit to you or to others from you joining this research. However, possible benefits include

- If you are belonging to the interventional group, you are eligible to attend five educational sessions that may help to improve the adherence to your medication

However, the result of the study may helpful to evaluate the medication adherence, medication self-management capacity and treatment experiences among chronic patients and the effect of an educational intervention in improving the medication adherence.

12. What happens to information about you?

We will make efforts to secure information about you. This includes using a code to identify you in our records instead of using your name. We will not identify you personally in any reports or publications about this research.

We cannot guarantee complete secrecy, but we will limit access to information about you. Only people who have a need to review information will have access. These people might include:

- Members of the research team and other Hamad Medical Corporation representatives whose work is related to the research or to protecting your rights and safety
- Representatives of the Ministry of Public Health Qatar and Hamad Medical Corporation who make sure the study is done properly and that your rights and safety are protected
- Your doctors and nurses

13. What if you don't want to join?

You can say no and we will not hold it against you.

14. What if you join but change your mind?

You can stop participating at any time and we will not hold it against you.

If you stop participating or withdrawing the consent, we will delete information that we have already collected about you.

15. What else should you know?

This research is funded by Hamad Medical Corporation

If you agree to take part in this research, we will provide you 100 QAR for each visit for your travel, time and effort.

RESEARCH CONSENT FORM

Signature Page for Capable Adult

Volunteer

I voluntarily agree to join the research described in this form.

Printed Name of Volunteer

Signature of Volunteer Date

Person Obtaining Consent

I document that:

- *I (or another member of the research team) have fully explained this research to the volunteer.*
- *I have personally evaluated the volunteer's understanding of the research and obtained their voluntary agreement.*

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

Witness (if applicable)

I document that the information in this form (and any other written information) was accurately explained to the volunteer, who appears to have understood and freely given Consent to join the research.

Printed Name of Witness

Signature of Witness Date

Appendix B: Data Storage Guidance

Instructions: If you plan to bank data for use in future research, please select the appropriate choice(s) below and place in the form according to the instructions. Delete this appendix from the form before uploading the form with your IRB application.

If you will destroy all links between the data and volunteer identities before banking the data for future use, paste the following paragraph in Section 12:

> We plan to use data from this study in other projects in the future. This might include sharing the data with other researchers. Before we store the data for future use, we will destroy all links between your identity and the data about you.

If you will bank the data with a coded link between the data and volunteer identities, add study-specific information to the following paragraph and paste it in Section 12:

> We plan to use data from this study in other projects in the future. This might include sharing the data with other researchers. Although we will keep a link between your identity and the data about you [choose one: we will not provide that link to anyone we share the data with; we will destroy the link before providing data to anyone outside the research team].

*If you will contribute **genetic** data to any data repositories, such as the NIH GWAS, add the following to the paragraph you chose above:*

> Information from analyses of your samples and medical information will be put into databases along with information from other volunteers. This will help researchers around the world.
>
> These databases will not include your name, telephone number or other information that directly identifies you.