

The effect of diabetes self efficacy enhancing intervention on diabetes self care management behaviors and psychological wellbeing among Jordanian type two diabetes patients.

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Registration date 23/10/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/01/2015	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Type 2 diabetes is a long-term condition where the body doesn't produce enough insulin to function properly or, alternatively, the cells of the body don't react well to insulin. This can cause blood sugar levels to become too high and, if left untreated, can lead to a number of health problems including heart disease, stroke, kidney disease, eyesight problems and nerve damage. People with type 2 diabetes have to look after their health very carefully. This includes eating a healthy diet, taking regular exercise, limiting the amount of alcohol they drink and making sure that they know when to seek medical attention for any health concerns that they may have. Here, we want to test a new self-help programme (diabetes self-efficacy enhancing intervention) for people who have type 2 diabetes. We want to see if the intervention leads to improvements in patients feeling more confident about managing their condition, psychological wellbeing and self-care management behaviours.

Who can participate?

Jordanian patients aged at least 20 years, diagnosed with type 2 diabetes and being treated at the diabetes specialized centre in Amman-Jordan.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) receive their usual care and the new diabetes self-efficacy enhancing intervention. Those in group 2 (control group) receive their usual care. The intervention consists of watching a DVD, diabetes self-care management booklets, two counselling sessions and follow-up telephone calls.

What are the possible benefits and risks of participating?

There are several potential benefits to this study. The intervention is designed to help people self-manage their disease and maintain a healthy lifestyle, solve problems and make an action plan. Risks are minimal. Patients displaying psychological stress will be informed by the researcher to stop participating in the trial.

Where is the study run from?
The University of Jordan (Jordan)

When is the study starting and how long is it expected to run for?
May 2014 to December 2014.

Who is funding the study?
Investigator initiated and funded (Jordan)

Who is the main contact?
Mrs Zainab Albikawi
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Contact information

Type(s)
Scientific

Contact name
Mrs Zainab Albikawi

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Amman-Jordan
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Additional identifiers

Protocol serial number
17203

Study information

Scientific Title
The effect of diabetes self efficacy enhancing intervention on diabetes self care management behaviors and psychological wellbeing among Jordanian type two diabetes patients: a randomized clinical trial

Study objectives

1. Patients who participated in diabetes self efficacy enhancing intervention (DSEEIP) had higher levels of DM (diabetes mellitus) self care management behaviors following completion of the DSEEIP at 10 weeks post-intervention, and at a three month post-intervention follow-up evaluation, than who did not receive the intervention.
2. Patients who participated in diabetes self efficacy enhancing intervention (DSEEIP) had higher levels of DM self-efficacy following completion of the DSEEIP at 2 weeks post-intervention, and at a three month post-intervention follow-up evaluation, than who did not receive the intervention.
3. Patients who participated in diabetes self efficacy enhancing intervention (DSEEIP) will have

higher levels of psychological wellbeing following completion of the DSEEIP at 2 weeks post-intervention, and at a three month post-intervention follow-up evaluation, than who did not receive the intervention

3.1. Additional Question

Are there differences in the control and intervention group baseline scores for the three outcome variables based on the demographic and disease history data?

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Jordan Ethical Committee, December 2013

Study design

Randomized controlled trial design

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type two diabetes mellitis

Interventions

The study intervention is based on self efficacy theory and consists of:

1. DVD, Diabetes Self care management booklets
2. Two rehearsal counseling sessions
3. Follow-up telephone calls

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Study Variable/Instruments:

1. Self Efficacy: The Diabetes Self efficacy Scale.
2. Self care management: Summary of Diabetes Self care management Activities (SDSCA), 12 items.
3. Psychological wellbeing: An Arabic version of the Depression Anxiety Stress Scales, DASS-21
4. The Demographic and disease history Questionnaire: Constructed by the current study researcher

The time points for data collection are as the following: screening (pre -intervention or baseline), 2 weeks following screening (post intervention), and 3 months follow up.

Key secondary outcome(s)

N/A

Completion date

01/12/2014

Eligibility

Key inclusion criteria

1. Patients should satisfied clinical criteria for DM2 (diabetes type 2)
2. Patient with DM2 who are taking oral agents
3. Patient can be at any stage of their DM diagnosis, length of diagnosis is not a limiting factor in recruitment
4. Patients are required to speak and read Arabic
5. Patients are required to be equal or over the age of 20 years
6. To be eligible for participation in the current study, the patients had to have average score of less than 6.5 out of 8 on DSES
7. Patients are required to have a telephone or mobile in their residence and able to use it effectively

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients had major complications which would interfere with self-care management behaviors (e.g. legally blind, severe stroke, or undertaking kidney dialysis); patients health records will be checked for the presence of any major DM complications
2. Patients currently managing blood glucose levels with the use of insulin injections alone
3. Patients with cognitive impairment
4. Patients who are not able to communicate
5. Patient with any mental or psychiatric illness, patients health records will be checked for that.

Date of first enrolment

01/05/2014

Date of final enrolment

01/12/2014

Locations

Countries of recruitment

Jordan

Study participating centre
Amman-Jordan
Amman
Jordan
00962

Sponsor information

Organisation
The University of Jordan (Jordan)

ROR
<https://ror.org/05k89ew48>

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Jordan)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration