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

Submission date
25/04/2014

Recruitment status
No longer recruiting

Registration date
23/10/2014

Overall study status
Completed

Last Edited
20/01/2015

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 doesnt produce enough insulin to function properly or, alternatively, the cells of the body dont 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 (Jordon)

Who is the main contact?
Mrs Zainab Albikawi
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Contact information

Type(s)
Scientific

Contact name
Mrs Zainab Albikawi

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 mellitis) 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 Jordon Ethical Committee, December 2013

Study design
Randomized controlled trial design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Demographic data sheet

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 measure
Study VariableInstruments:
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.

Secondary outcome measures
N/A

Overall study start date
01/05/2014

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

Age group
Adult

Sex
Both

Target number of participants
168

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)

Sponsor details
c/o Zainab Albikawi
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Sponsor type
University/education

ROR
https://ror.org/05k89ew48

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded (Jordan)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration