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Evaluation of the impact of a PsychoEducational intervention on knowledge levels and Psychological outcomes for schizophrenic patients and their carers in Jordan

Submission date
27/11/2013

Recruitment status
No longer recruiting

Registration date
16/12/2013

Overall study status
Completed

Last Edited
27/10/2015

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Schizophrenia is one of the most serious forms of mental illness among people being treated in psychiatric clinics in developing and developed countries, and can be chronic , recurrent, disabling and debilitating (affecting the ability to carry on with regular activities). The aims of this study are to examine the effectiveness of delivering a psychoeducational intervention, in booklet form, on schizophrenia knowledge of patients and caregivers, positive and negative schizophrenia symptoms, relapse rate of patients, burden of care, and quality of life of caregivers.

Who can participate?
The study aims to recruit about 144 men and women living with schizophrenia or schizoaffective disorder and their primary caregivers, age > 18 years from outpatient clinics in four mental health clinics in Jordan.

What does the study involve?
At baseline (before the start of the intervention), participants were invited to sign a consent form and complete baseline measures (knowledge level, schizophrenia symptoms and relapse rate). Baseline measures for carers are knowledge level, burden of care and quality of life. Participants were randomly allocated to one of two groups: participants in the intervention arm of the study received a psychoeducation booklet each fortnight plus treatment as usual in the clinic for 12 weeks. On the other hand, participants in control group received treatment as usual in the outpatient clinic for 12 weeks. The outcomes were again measured at the end of the treatment and at three months follow-up.

What are the possible benefits and risks of participating?
Potential benefits from this study include increasing patients' knowledge about schizophrenia,

improved positive and negative symptoms associated with schizophrenia and reduced relapse rate. Potential benefits to caregivers are improved quality of life, enhanced knowledge level and reduced burden of care.

Where is the study run from?
In the four major outpatient clinics for mental health in Jordan.

When is the study starting and how long is it expected to run for?
Recruitment started at the end of 2012. Participants were enrolled on the study for a period of 6 months.

Who is funding the study?
Islamic Development Bank (Saudi Arabia).

Who is the main contact?
Professor Patrick Callaghan
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Evaluation of the impact of a PsychoEducational intervention on knowledge levels and Psychological outcomes for people diagnosed with schizophrenia and their carers in Jordan: A randomized controlled trial and process evaluation

Acronym
PEP

Study objectives
Patients who receive psychoeducation will show equal or greater knowledge of schizophrenia, improved psychotic symptoms and lower relapse rates at post-intervention and follow-up than patients who receive treatment as usual (TAU).

Carers who receive psychoeducation will show equal or greater knowledge of schizophrenia, lower burden of care and improved quality of life post-intervention and follow-up than carers who receive TAU.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Jordanian Ministry of Health Ethics Committee, 10/08/2012
2. University of Nottingham Medical Ethical Committee, 23/07/2012

Study design
Placebo-controlled single-blind randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Schizophrenia

Interventions
Intervention: treatment as usual + psychoeducational intervention
Based on Atkinson and Coia model. It consists of six booklets each fortnight covering essential topics to patients and carers:
1. General information about schizophrenia

2. Anti-psychotic medication effects and side effects
3. Relapse signs
4. Problem solving
5. Coping with Illness

Control:
Treatment as usual for 12 weeks.

Patients and carers will be followed up at baseline, end of treatment and three months follow-up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Patients' primary outcome is knowledge level about schizophrenia measured by knowledge about schizophrenia questionnaires (KASQ)
2. Carers' primary outcome is knowledge level about schizophrenia measured by knowledge about schizophrenia questionnaires (KASQ)

All outcomes measured at baseline, end of treatment and three months follow up.

Secondary outcome measures
Patient:
1. Schizophrenia symptoms are measured by the positive and negative syndrome scale (PANSS)
2. Relapse with hospitalization is measured by the number of mental hospital re-admissions
3. Relapse with medication is calculated by the number of anti-psychotic drug dosage increases

Caregivers:
1. Burden of care is measured by Family Burden Interview Schedule (FBIS)
2. Quality of life is measured by Schizophrenia-Caregiver Quality of Life (S-CQoL)

All outcomes measured at baseline, end of treatment and three months follow up.

Overall study start date
01/09/2012

Completion date
01/05/2013

Eligibility

Key inclusion criteria
Patients:
1. Diagnosed with schizophrenia or schizoaffective disorder based on the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV)

2. Able to read Arabic or English language
3. Written consent
5. Aged 18 or over, either sex

Caregivers:
1. Primary caregivers - caregivers who mostly involved in patients' care
2. Able to read Arabic or English language
3. Written consent
5. Aged 18 or over, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
144

Key exclusion criteria
Patients:
1. Any learning disability
2. Presence of known organic mental disorder
3. Had a history of substance abuse or current substance abuse
4. Living alone without caregivers or attended any psychosocial intervention previously

Caregivers:
Involved in caring for more than one patient with mental disorder

Date of first enrolment
01/09/2012

Date of final enrolment
01/05/2013

Locations

Countries of recruitment
England

Jordan

United Kingdom

Study participating centre
University of Nottingham
Nottingham
United Kingdom
NG7 2HA

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Queens Medical Centre
Nottingham
England
United Kingdom
NG7 2HA

Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Other

Funder Name
Islamic Development Bank (Saudi Arabia)

Alternative Name(s)
IDB

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Saudi Arabia

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/01/2014		Yes	No
Results article	results	08/04/2015		Yes	No