

Adherence therapy for people with hypertension

Submission date 23/07/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/08/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/05/2020	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

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

Adherence therapy for people with hypertension: a randomised controlled trial

Acronym

AT BMQ

Study objectives

Current information as of 15/03/10:

1. Advanced Therapy (AT) reduces systolic blood pressure (SBP) in Jordanian people with hypertension at seven weeks, compared to treatments as usual.
2. AT reduce diastolic blood pressure (DBP) in Jordanian people with hypertension compared to treatments as usual.
3. AT improves adherence in Jordanian people with hypertension compared to treatments as usual.
4. AT improves attitudes and beliefs toward medication in Jordanian people with hypertension compared to usual care.

Initial information at time of registration:

1. Adherence therapy (AT) reduces systolic blood pressure in Jordanian people with hypertension at eight weeks, compared to treatment as usual
2. AT improves adherence in Jordanian people with hypertension compared to treatment as usual
3. AT improves attitudes and beliefs toward medication in Jordanian people with hypertension compared to usual care

Please note that as of 15/03/10 this record has been updated to include changes in the hypothesis, inclusion criteria and secondary outcomes. All updates can be found in the relevant field with the above update date.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Jordanian Ministry of Health Ethics Committee approved on the 18th June 2009
2. University of East Anglia Ethical Committee approved on the 23rd July 2009

Study design

Single-blind exploratory randomised parallel group controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

Hypertension

Interventions

Intervention:

Based on cognitive behavioural approaches derived from compliance therapy, adherence therapy consists of:

1. Engagement
2. Assessment
3. Ratings of readiness to take medication
4. Therapy
5. Evaluation

The therapist works in a flexible, patient-centered and structured way to promote a shared decision with the patient about treatment. Patients receive eight weekly sessions of adherence therapy.

Control:

Treatment as usual for 8 weeks.

Patients will be followed up for one month after intervention/control.

Contact Details for Joint Principal Investigators:

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Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Systolic blood pressure reduction, measured in mmHg, measured after one month from the end of sessions.

Secondary outcome measures

1. Correct dosing of drugs, defined as percentage of prescribed doses taken during the research interval. Assessed by pill-counting after one month from the end of sessions for each participant according to the given doses.
2. Attitude and beliefs with medication, measured by using the Beliefs About Medication Questionnaire (BMQ)
3. Satisfaction with adherence therapy, determined by interviews conducted one month from the end of sessions

Added 15/03/10:

4. Patient diastolic blood pressure measured in mmHg

Overall study start date

10/08/2009

Completion date

30/12/2009

Eligibility**Key inclusion criteria**

1. Diagnosed with hypertension
2. On monthly follow up schedule
3. Blood pressure greater than 140/90 mmHg
4. Written consent
5. Aged above or equal to 18 years, either sex

Added 15/03/10:

6. Non-adhered patients based on Morisky Medication Adherence Scale (MMAS)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

136

Total final enrolment

Key exclusion criteria

1. Diabetes
2. Congestive heart failure
3. Mentally ill
4. Serious disease conditions
5. Pregnant women with hypertension

Date of first enrolment

10/08/2009

Date of final enrolment

30/12/2009

Locations**Countries of recruitment**

England

Jordan

United Kingdom

Study participating centre

School of Nursing and Midwifery

Norwich

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Sponsor information**Organisation**

University of East Anglia (UK)

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Sponsor type

University/education

Website

<http://www.uea.ac.uk/>

ROR

<https://ror.org/026k5mg93>

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2012	21/05/2020	Yes	No