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Adherence therapy for people with hypertension

Submission date	Recruitment status	[ ] Prospectively registered
23/07/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/08/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/05/2020	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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. Unversity 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

Study type(s)
Treatment

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.

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Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Systolic blood pressure reduction, measured in mmHg, measured after one month from the end of sessions.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
136

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
United Kingdom

England

Jordan

Study participating centre
School of Nursing and Midwifery
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Sponsor information

Organisation
University of East Anglia (UK)

ROR
https://ror.org/026k5mg93

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2012	21/05/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes