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Engaging patients in managing hypertension: patient experience with self-monitoring of blood pressure

Submission date
11/02/2020

Recruitment status
No longer recruiting

Registration date
03/04/2020

Overall study status
Completed

Last Edited
27/05/2021

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Self-monitoring of blood pressure has the potential to engage patients, increase the accuracy of measurement, and improve management, and it has been endorsed by key professional organizations. However, little is known about how it is perceived and experienced by patients, and how information and counseling interventions can enhance its effects over time. This study is conducted in Lebanon where hypertension and overweight are prevalent and success in reducing hypertension has been limited. This project includes a situation analysis on the context of hypertension management, and a pilot study that assesses the feasibility and acceptability of an intervention built around self-monitoring of blood pressure and health education, and measures its effect on the management of hypertension in a sample of patients.

Who can participate?
Hypertensive patients recruited from physicians' waiting rooms in two primary health care centers and a tertiary health care center in Beirut. Patients are eligible if they were Lebanese adults (18+) with a prior diagnosis of hypertension.

What does the study involve?
Participants are randomly allocated by the research team to either home self-monitoring of blood pressure with educational sessions, or the standard of care group. Face-to-face interviews are conducted with all participants at the start and 6 weeks later.

What are the possible benefits and risks of participating?
Participation in this study does not involve any physical risk or emotional risk to the patient beyond the risks of daily life. Participating in this study is beneficial to patients in the pilot intervention group, as it would lead to increased awareness of high blood pressure, its causes, management including the use of the self-monitoring blood pressure machines, and recommended lifestyle changes. Patients in the standard of care group would also benefit from added information and awareness, thanks to conversations in the course of the survey and

receipt of educational materials. Because of the possibility that the provision of self-monitoring devices to patients may lead to anxiety regarding high blood pressure readings, the researchers provided information on how to deal with anxiety in this context and when to seek care.

Where is the study run from?
1. American University of Beirut Medical Center (Lebanon)
2. Howard Karagheusian Commemorative Corporation (Lebanon)
3. Amel Association (Lebanon)

When is the study starting and how long is it expected to run for?
April 2016 to April 2019

Who is funding the study?
Harvard Medical School Center for Global Health Delivery (Dubai)

Who is the main contact?
Dr Hala Ghattas
hg15@aub.edu.lb

Contact information

Type(s)
Scientific

Contact name
Dr Chaza Akik

Contact details
Bliss Street
Beirut
Lebanon
1107
+961 (0)3410366
ca36@aub.edu.lb

Type(s)
Scientific

Contact name
Dr Hala Ghattas

Contact details
Principal Investigator
Center for Research on Population and Health, Faculty of Health Sciences
American University of Beirut
Van Dyck Building
Room 338
Beirut
Lebanon

-
+961 (0)1 350000 ext: 4679
hg15@aub.edu.lb

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
FHS.HG.13/SBS-2017-0612

Study information

Scientific Title
Engaging patients in managing hypertension: patient experience with self-monitoring of blood pressure

Study objectives
Self-monitoring of blood pressure has the potential to engage patients, increase the accuracy of measurement, and improve management, and it has been endorsed by key professional organizations. The researchers sought to investigate how it is perceived and experienced by patients, and how information and counseling interventions can enhance its effects over time, specifically in Arab countries, where hypertension and overweight are prevalent and success in reducing hypertension has been limited.

This project includes:
1. A situation analysis on the context of hypertension management
2. A pilot study that assesses the feasibility and acceptability of an intervention built around self-monitoring of blood pressure and health education, and measures its effect on the management of hypertension in a sample of patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/06/2018, 04/10/2018, American University of Beirut Institutional Review Board (PO Box 11-0236 (F15), Riad El Solh 1107 2020, Beirut, Lebanon; Tel: +961 (0)1 350000 ext: 5445; Email: irb@aub.edu.lb), ref: FHS.HG.13

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)

Quality of life

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

Interventions
Hypertensive patients were recruited from physicians' waiting rooms in two primary and one tertiary health care centers in Beirut.

Patients who agreed to participate in the study were randomly allocated by the research team to either home self-monitoring of blood pressure with educational sessions; or standard of care group, based on a computer-generated series of numbers.

Face-to-face interviews were conducted with all participants at baseline and 6 weeks later at endline.

Intervention Type
Behavioural

Primary outcome(s)
1. Feasibility of the intervention, assessed in the self-monitoring of blood pressure group using three indicators at endline (6 weeks):
1.1. Recruitment rates and retention rates (i.e. the percentage of patients from the self-monitoring group who completed the 6-week study)
1.2. The extent to which participants adhere to the BP measurements protocol
1.3. Responses of patients to the questions of how likely they are to continue using the device on a regular basis and to discuss the educational information with their acquaintances
2. Acceptability of the intervention, measured in the endline questionnaire of the self-monitoring group by responses to open-ended questions about patients' experiences and opinions regarding self-monitoring of BP and educational materials
3. Blood pressure measured at baseline and endline

Key secondary outcome(s))
1. Understanding of the information provided during educational sessions measured using a questionnaire at baseline and endline
2. Patient engagement:
2.1. Reported changes in lifestyle habits over the course of the 6-week study, including physical activity levels, salt intake, dietary intake, stress management, and smoking habits, assessed during the endline interview
2.2. Medication adherence assessed using the 8-item Morisky Medication Adherence Scale (MMAS-8) at baseline and endline

Completion date
02/04/2019

Eligibility

Key inclusion criteria
1. Lebanese adults (aged 18+)
2. Prior diagnosis of hypertension

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
80

Key exclusion criteria
1. Spouse is a participant in the study
2. Physical or mental health conditions that would interfere with adequate monitoring of BP

Date of first enrolment
01/07/2018

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
Lebanon

Study participating centre
American University of Beirut Medical Center
Bliss Street
Beirut
Lebanon
1107

Study participating centre
Howard Karagheusian Commemorative Corporation
Burj Hammoud
Beirut
Lebanon
000

Study participating centre
Amel Association
Haret Hreik
Beirut
Lebanon
000

Sponsor information

Organisation
American University of Beirut

ROR
https://ror.org/04pznsd21

Funder(s)

Funder type
University/education

Funder Name
Harvard Medical School Center for Global Health Delivery - Dubai

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Hala Ghattas (hg15@aub.edu.lb). Data can be made available after an embargo period of 2 years. All data are de-identified, and a de-identified subset of data can be shared upon submission of a research proposal to the study team.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		27/05/2021	27/05/2021	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes