WS 1
HOW TO SET UP A RESEARCH STUDY

7th PCNE Working conference, Manchester

WS 1 How to set up a research study

Aim: to introduce the novice researcher to the key elements of setting up intervention studies in community pharmacy practice.

PCNE 2011

Structure of the WS

- What is an intervention study (IS)?
  - Lecture, discussion
- Decision about a research question
- Design an IS
  - Discussion: Development of a protocol for our IS
  - Followed a check list for IS

Parts of a check-list for IS

- Development of a protocol
- Research team /collaborators (part of the protocol)
- Budget
- Piloting
- Implementing the intervention
- Analysis of findings
- Publication

Outline of a protocol

- Title, background
- Research question, aim(s) and objectives
- Study design
- Method and setting
- Research sites and research participants
- Data collection methods
- Analysis of findings
- Timeframe
- Budget
- Ethical approval and other forms of regulation

Study protocol

- Research question
  - Do pharmaceutical care interventions improve blood pressure control in patients with uncontrolled hypertension?
- Aim
  - To examine the effect of pharmaceutical care by community pharmacists to patients with hypertension to improve their blood pressure.

Objectives

- To develop a pharmaceutical care model
  - qualitative study with input from GPs, pharmacists and patients
- To test the feasibility in a pilot study
- To evaluate the pharmaceutical care model in a RCT
- Follow up with qualitative work

Inclusion criteria

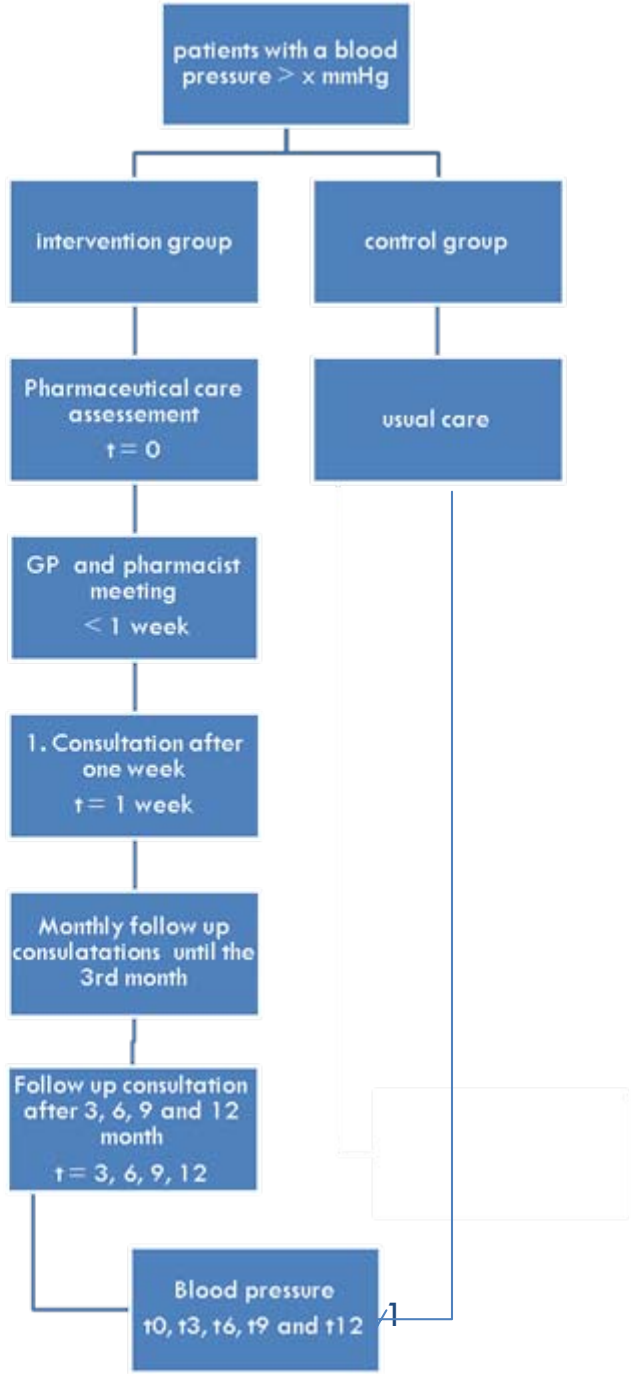
- Patient
  - Confirmed diagnosis of refractory hypertension
  - BP > X mmHg (syst/diast.)
  - Taking medication for hypertension
  - Able to come to the pharmacy
  - Regularly using a participating pharmacy
  - Not cognitive impaired
  - Given informed consent

Inclusion criteria

- Pharmacy
  - Community pharmacy
  - Consultation area
  - Keep medication records
- Pharmacist / Physicians
  - Attend training together
  - Consent to take part

Training

- Overview of clinical condition + treatment
- Recruitment, consent
- Implementing the intervention
- Documentation
- Data collection


patients with a blood pressure > x mmHg
intervention group
control group
Pharmaceutical care assessement
t = 0
usual care
GP and pharmacist meeting
< 1 week
1. Consultation after one week
t = 1 week
Monthly follow up consulatations until the 3rd month
Follow up consultation after 3, 6, 9 and 12 month
t = 3, 6, 9, 12
Blood pressure
t0, t3, t6, t9 and t12

Measuring outcomes

- Primary outcome
  - Reduction in blood pressure (measured by a blinded assessor following protocol)
- Secondary outcome
  - Identification and resolution of DRP
  - Lifestyle changes
  - Health care utilization (contacts with GP)
  - Quality of life (t_0, t_{12})


Thanks!!