

Development of an RCT for a non-treatment intervention: The Care Navigation Trial

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The Research Team

- Serious & Continuing Illness Policy & Practice Study (SCIPPS)
 - Solutions: health & QoL
 - Focus on coronary, respiratory & diabetes
 - ↓ avoidable hospital admissions
 - Current strategies
 - Interventions & evaluations

The Area Health Service

- Sydney West Area Health Service (SWAHS)
 - Ageing population
 - Chronic disease a major focus
 - PITCCH redesign project: developed intervention

The Intervention: Care Navigation

- ↑ patient care in hospital
 - ID frequent flyers
 - Profile patient
 - Streamlining referrals
- ↑ access to care from home
 - ID home-based needs for condition management
 - ID suitable community programs
 - Discuss:
 - Community health providers
 - Patient
- Ongoing care, not just episodic
 - ↓ need for ED/hospitalisation

Evaluation of Care Navigation

- SCIPPS volunteered to evaluate Care Navigation

Methods for evaluation
Systematic review (comparison of RCTs)
Randomised controlled trial
Cluster trial
Cohort study (before/after)

- Levels of evidence – value of information, measure of certainty
- Randomised allocation between new intervention & control groups
 - Equal confounding factors
 - Only difference is the intervention

Study design

Eligible patients present to Nepean Hospital ED:

- 3 previous presentations in 12 months, and either
 - 70+ years old
 - 45-69 years, 1+ presentation CHD or COPD

RANDOMISE

Standard Care

Care Navigation

3 month follow-up

6 month follow-up

12 month follow-up

- EQ-5D
- Re-presentations
- Re-admissions
- Days in hospital

Application of RCT to non-treatment study

	Treatment studies	Non-treatment studies
Intervention type	Discreet physical intervention, e.g. drug, radiotherapy, surgical technique, device	Multiple <u>work process adjustments</u> of staff roles at <u>multiple areas</u> within the hospital, affecting many different roles, altering patient flow
Intervention protocol	Protocol document of precisely defined instructions, e.g. dispensing, dosage, timing	Conceptual idea developed for SWAHS, to be adapted for individual hospitals
Record of intervention delivery	Precise record keeping requirements regarding compliance & adherence	Little or no record keeping of areas being changed, i.e. no record of referrals
Research staff	Hospital research staff. Principal Investigator expertise in intervention & methodology	Unfamiliar external staff PI unfamiliar with research methods All unfamiliar with intervention

Preparation stage: Protocol

- Guidelines & templates
 - ICH GCP guidelines (methodology, international)
 - NHMRC National Statement (ethics, Australia)
 - Grant research plan (NHMRC Partnerships)
- Approvals
 - Ethics (SAC, HREC)
 - Governance (Institution/organisation)

Preparation stage: Data quality

- Compliance of intervention delivery
 - Checklists for nursing staff
 - Proof, i.e. referrals & discharge plans
- Adherence of participant to advice
 - Record of patient receiving community care
- Accuracy of data collection
 - Transcription from source documentation (CRFs)
 - Data entry
 - Data storage (data field validation rules)
 - Data extraction (data table relationships)

Next step

- Finalise data & QA requirements (manual)
- Final approvals
- Implementation
 - Training for uni, hospital & community staff
 - Recruitment of 500 participants
- Ongoing QA checks
 - Timely
 - Feedback
 - Refresher training
- Recruitment starts 01 November 2009