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The HAPPI Study

Holistic Assessment and care Planning in Partnership Intervention Study: A feasibility randomised controlled trial

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HAPPI STUDY

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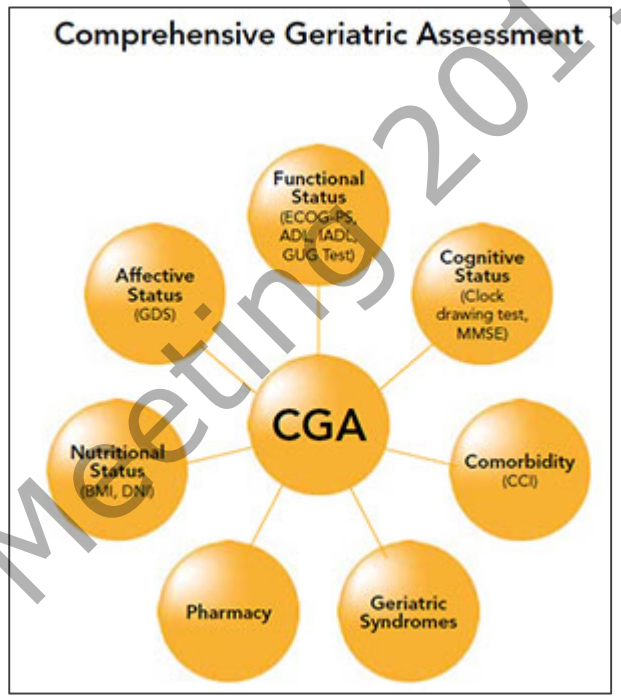
Background



But…..

The supporting evidence base is weak and making frailty integral to primary care has challenges:

- Acceptability of the concept to patients and clinicians
- Determining if CGA is feasible in primary care
- Convincing over-stretched primary care clinicians that this can improve patient outcomes and reduce workloads

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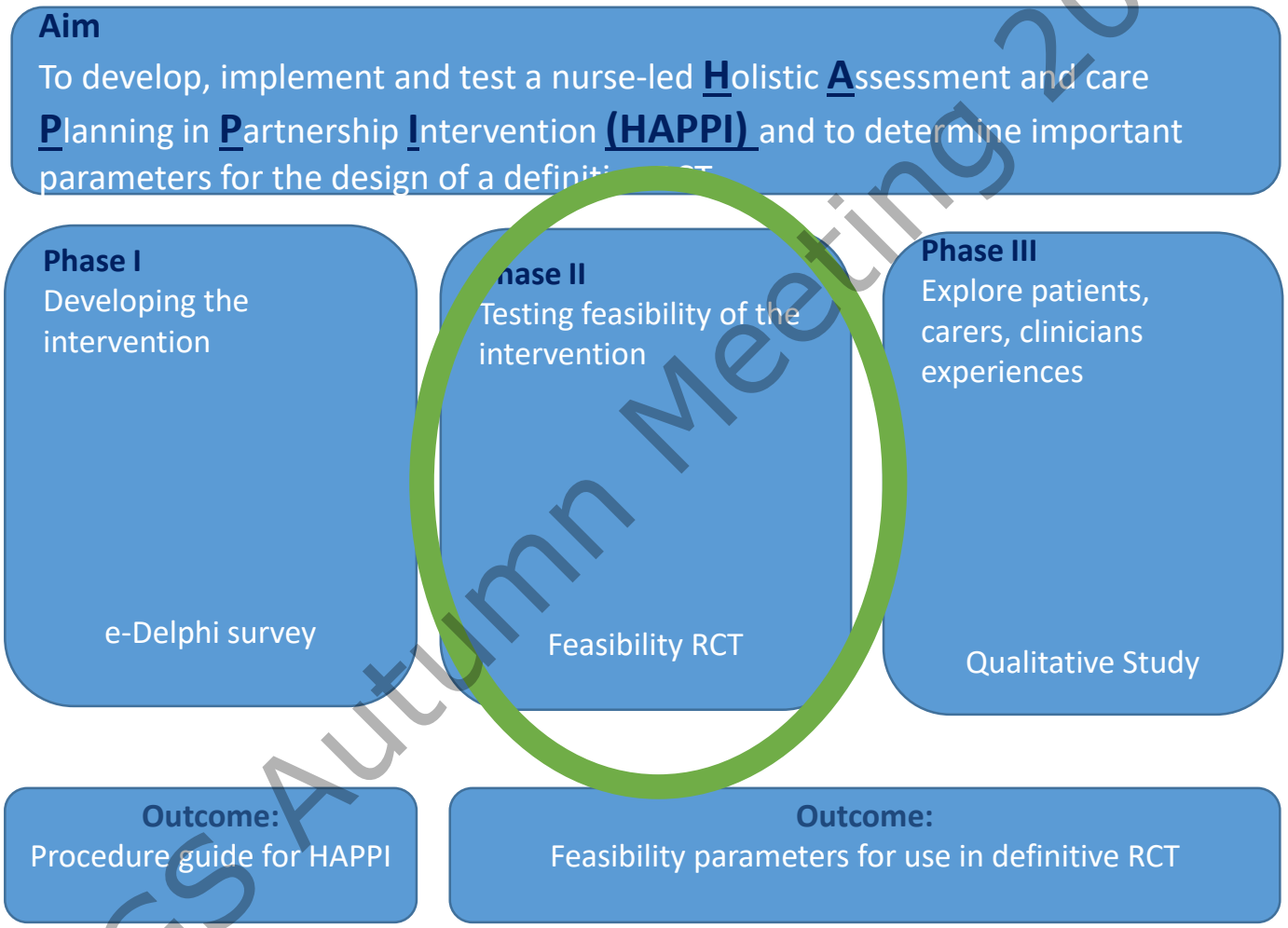
HAPPI: A Mixed Methods Feasibility Study



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The HAPPI fRCT

Aim:

- To conduct a cluster randomised, controlled feasibility study of a nurse-led assessment and care planning intervention
- To determine feasibility of delivering the intervention in primary care to older people with frailty.
- This includes testing potential trial methods to inform the design of a definitive randomised controlled trial (RCT).

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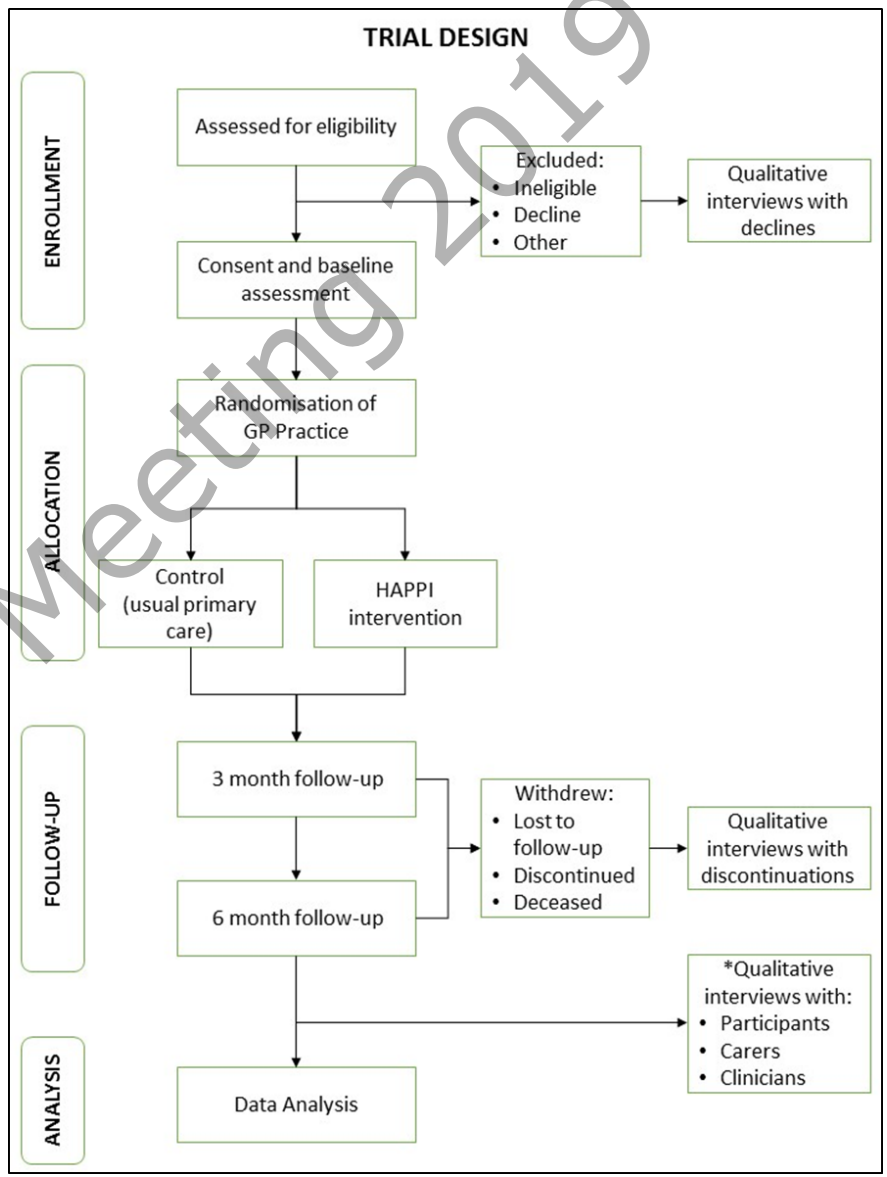
Trial Design

National Health Service Research Ethics Committee (REC reference: 18/LO/1354; IRAS project ID: 229210) 16/10/2018.

University of Plymouth Research Ethics Committee (Reference Number: 18/19-1027) 14/11/2018 .



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Methods: Randomisation

- Cluster randomisation at site level
- All participants in each general practice will be allocated to intervention or control
- Avoids contamination of control group and "intervention creep"
- Exact details of allocation algorithm determined between the trial statistician and PenCTU programming team

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Methods: Recruitment

- 60 moderately or severely frail participants aged 65 years and over
- Recruited from six sites (general practices) in Cornwall, UK
- Initial identification using the Electronic Frailty Index (eFI)
- Random sampling from eFI cohort
- Frailty confirmed using PRISMA-7 instrument
- Participant informed consent at home

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Eligibility

Eligible	Ineligible
Aged 65 years and over	In receipt of palliative care with limited life expectancy
Moderately frail eFI >0.24-0.36 or severely frail eFI > 0.36	Currently on the caseload of a community matron
Frailty confirmed by PRISMA7 instrument	
Able to give informed consent	
Living in own home/supported living accommodation	

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Data collection

- At baseline, three months and six months
- Participant – study questionnaires administered by research team
- Data from general practice
- Customised study database developed by Clinical Trials Unit

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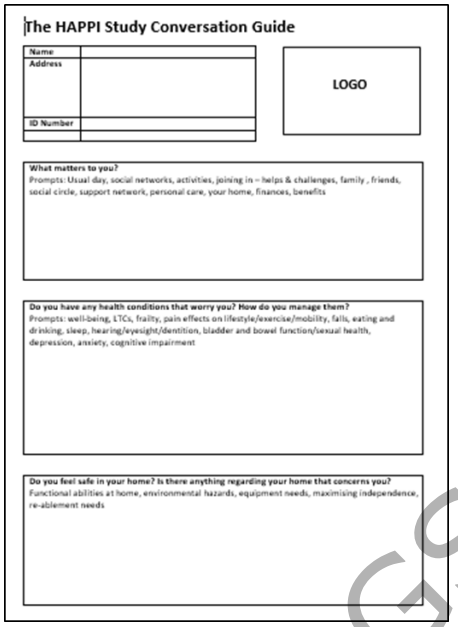
Intervention

- Intervention developed using e-Delphi methods (phase 1)
- Delivered by community matrons
- One assessment visit and up to six care planning visits conducted over a maximum of 12 weeks



The HAPPI Study Conversation Guide

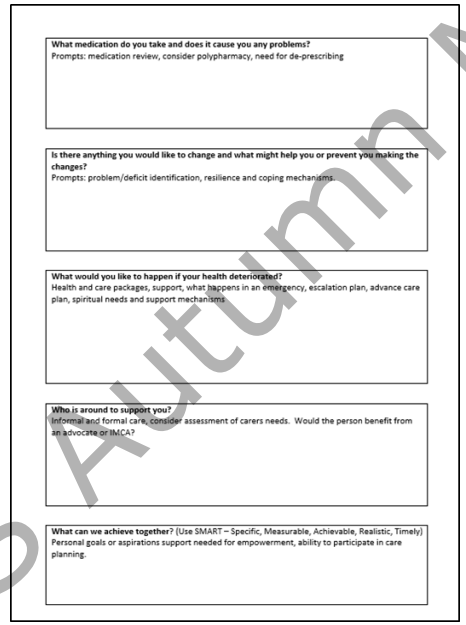
Name
Address
ID Number

LOGO

What matters to you?
Prompts: Usual day, social networks, activities, joining in – helps & challenges, family , friends, social circle, support network, personal care, your home, finances, benefits

Do you have any health conditions that worry you? How do you manage them?
Prompts: well-being, LTCs, frailty, pain effects on lifestyle/exercise/mobility, falls, eating and drinking, sleep, hearing/eyesight/dentition, bladder and bowel function/sexual health, depression, anxiety, cognitive impairment

Do you feel safe in your home? Is there anything regarding your home that concerns you?
Functional abilities at home, environmental hazards, equipment needs, maximising independence, re-ablement needs



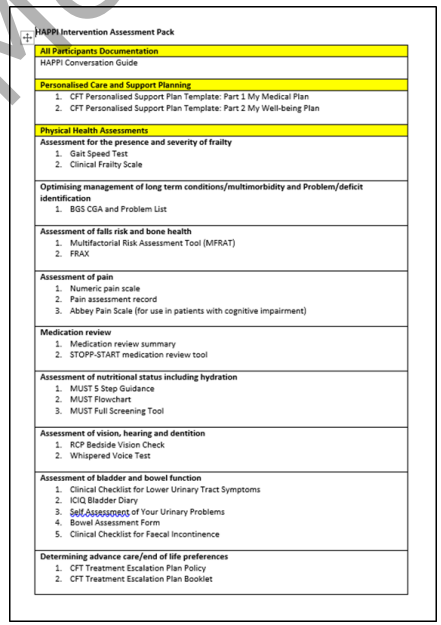
What medication do you take and does it cause you any problems?
Prompts: medication review, consider polypharmacy, need for de-prescribing

Is there anything you would like to change and what might help you or prevent you making the changes?
Prompts: problem/deficit identification, resilience and coping mechanisms.

What would you like to happen if your health deteriorated?
Health and care packages, support, what happens in an emergency, escalation plan, advance care plan, spiritual needs and support mechanisms

Who is around to support you?
Informal and formal care, consider assessment of carers needs. Would the person benefit from an advocate or IMCA?

What can we achieve together? (Use SMART – Specific, Measurable, Achievable, Realistic, Timely)
Personal goals or aspirations support needed for empowerment, ability to participate in care planning.



HAPPI Intervention Assessment Pack

All Participants Documentation
HAPPI Conversation Guide

Personalised Care and Support Planning
1. CFT Personalised Support Plan Template: Part 1 My Medical Plan
2. CFT Personalised Support Plan Template: Part 2 My Well-being Plan

Physical Health Assessments

Assessment for the presence and severity of frailty
1. Gait Speed Test
2. Clinical Frailty Scale

Optimising management of long term conditions/multimorbidity and Problem/deficit identification
1. BGS CGA and Problem List

Assessment of falls risk and bone health
1. Multifactorial Risk Assessment Tool (MFRAT)
2. FRAX

Assessment of pain
1. Numeric pain scale
2. Pain assessment record
3. Abbey Pain Scale (for use in patients with cognitive impairment)

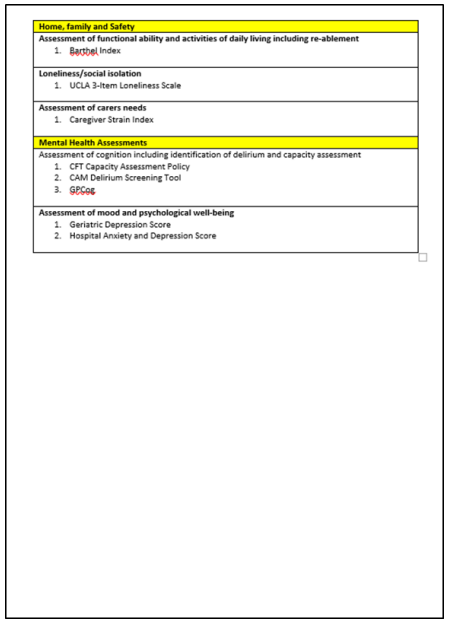
Medication review
1. Medication review summary
2. STOPP-START medication review tool

Assessment of nutritional status including hydration
1. MUST 5 Step Guidance
2. MUST Flowchart
3. MUST Full Screening Tool

Assessment of vision, hearing and dentition
1. RCP Bedside Vision Check
2. Whispered Voice Test

Assessment of bladder and bowel function
1. Clinical Checklist for Lower Urinary Tract Symptoms
2. ICIQ Bladder Diary
3. Self Assessment of Your Urinary Problems
4. Bowel Assessment Form
5. Clinical Checklist for Faecal Incontinence

Determining advance care/end of life preferences
1. CFT Treatment Escalation Plan Policy
2. CFT Treatment Escalation Plan Booklet



Home, family and Safety

Assessment of functional ability and activities of daily living including re-ablement
1. Barthel Index

Loneliness/social isolation
1. UCLA 3-Item Loneliness Scale

Assessment of carers needs
1. Caregiver Strain Index

Mental Health Assessments

Assessment of cognition including identification of delirium and capacity assessment
1. CFT Capacity Assessment Policy
2. CAM Delirium Screening Tool
3. GPCog

Assessment of mood and psychological well-being
1. Geriatric Depression Score
2. Hospital Anxiety and Depression Score

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Control

- “Usual care” for frailty in primary care
- This may include the management of long-term conditions, referrals to other services, prescribing of medications and routine vaccinations
- As part of the feasibility trial, components of usual care will be captured to standardise for the future definitive RCT

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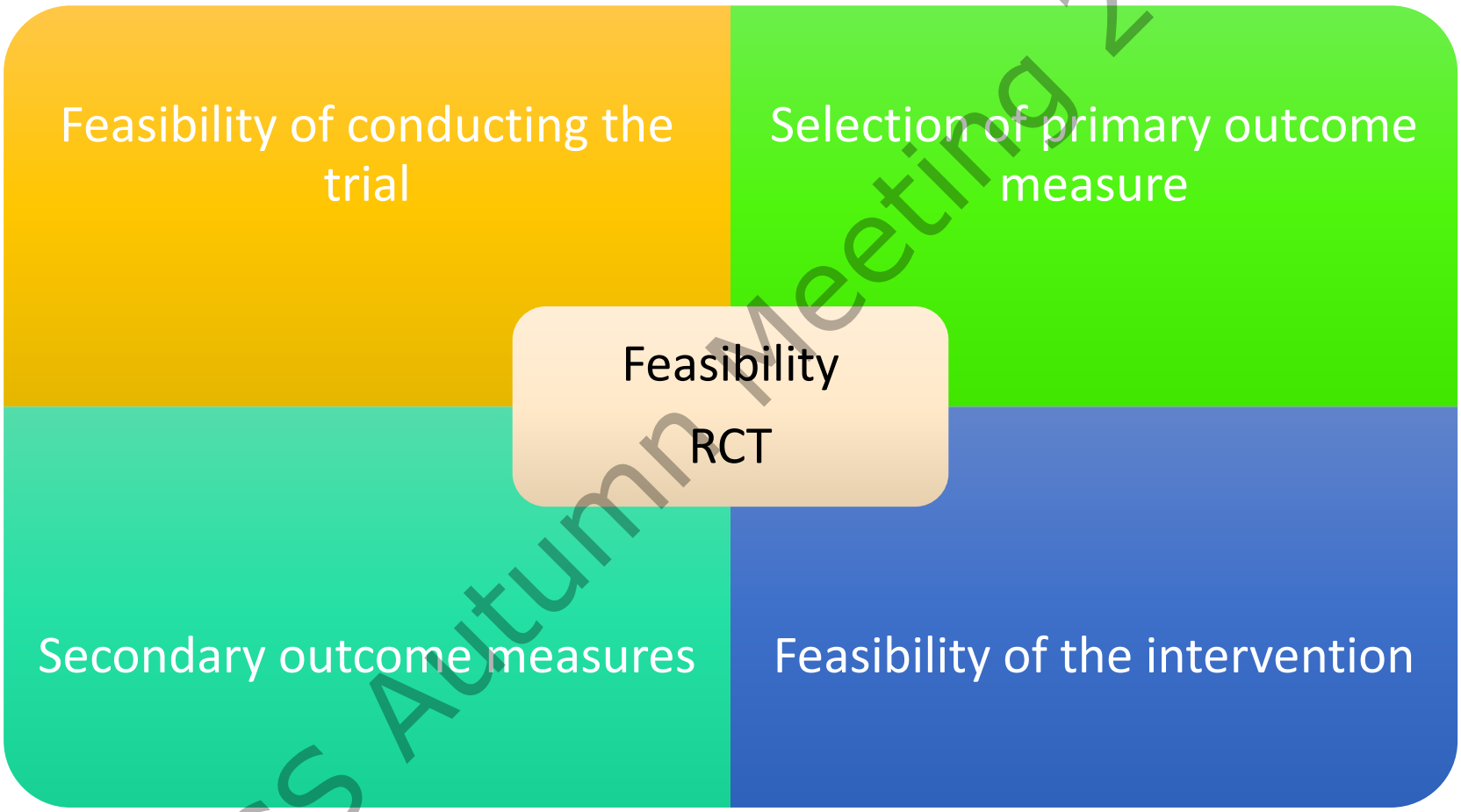
Outcomes



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Outcomes: Feasibility of the intervention

- Numbers of completed HAPPI intervention conversation guides and personalised care plan templates
- Assess degree of contamination by number of staff moving between intervention and control practices

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Outcomes: Feasibility of conducting the trial

- Number of GP practices expressing an interest in participating
- Number of GP practices screened for selection and reasons for non-selection
- Number of GP practices withdrawing from the study, timing and reason for withdrawal
- Number of GP practices failing to progress through implementation milestones and reasons for failure
- Numbers of participants screened as eligible, recruited, consented and followed up
- Numbers of participants identified using the electronic frailty index (eFI)
- Number of and timing of participant withdrawals from follow-up data collection, reasons for withdrawal, number of and timing of losses to follow-up

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Outcomes: Selection of primary & secondary outcome measures

Fidelity to protocol:

- Numbers of potential primary and secondary outcome measures completed at baseline and follow-up intervals
- Numbers of missing items for each potential primary and secondary outcome at each time-point
- Estimation of the feasibility of collecting data to estimate cost-effectiveness; EQ-5D-5L; add-on for economic evaluation

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Outcomes: Selection of primary & secondary outcome measures

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Participant Reported:

- Levels of loneliness and isolation measured by UCLA 3-Item Loneliness Scale
- Physical health and mobility, level of pain, mood and emotional health and health-related quality of life measured by the Medical Outcomes Study 36-Item Short Form Survey Instrument Version 1 (SF-36)
- Confidence in own ability to manage health and in role as participants in care measured by the Health Foundation LTC6 questionnaire
- Function measured by Barthel Index

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Outcomes: Selection of primary & secondary outcome measures

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Collected from General Practice Clinical Record:

- Polypharmacy – number of medications prescribed
- Mortality; date and cause of death
- Number of hospital admissions, readmissions and total number of days spent in hospital

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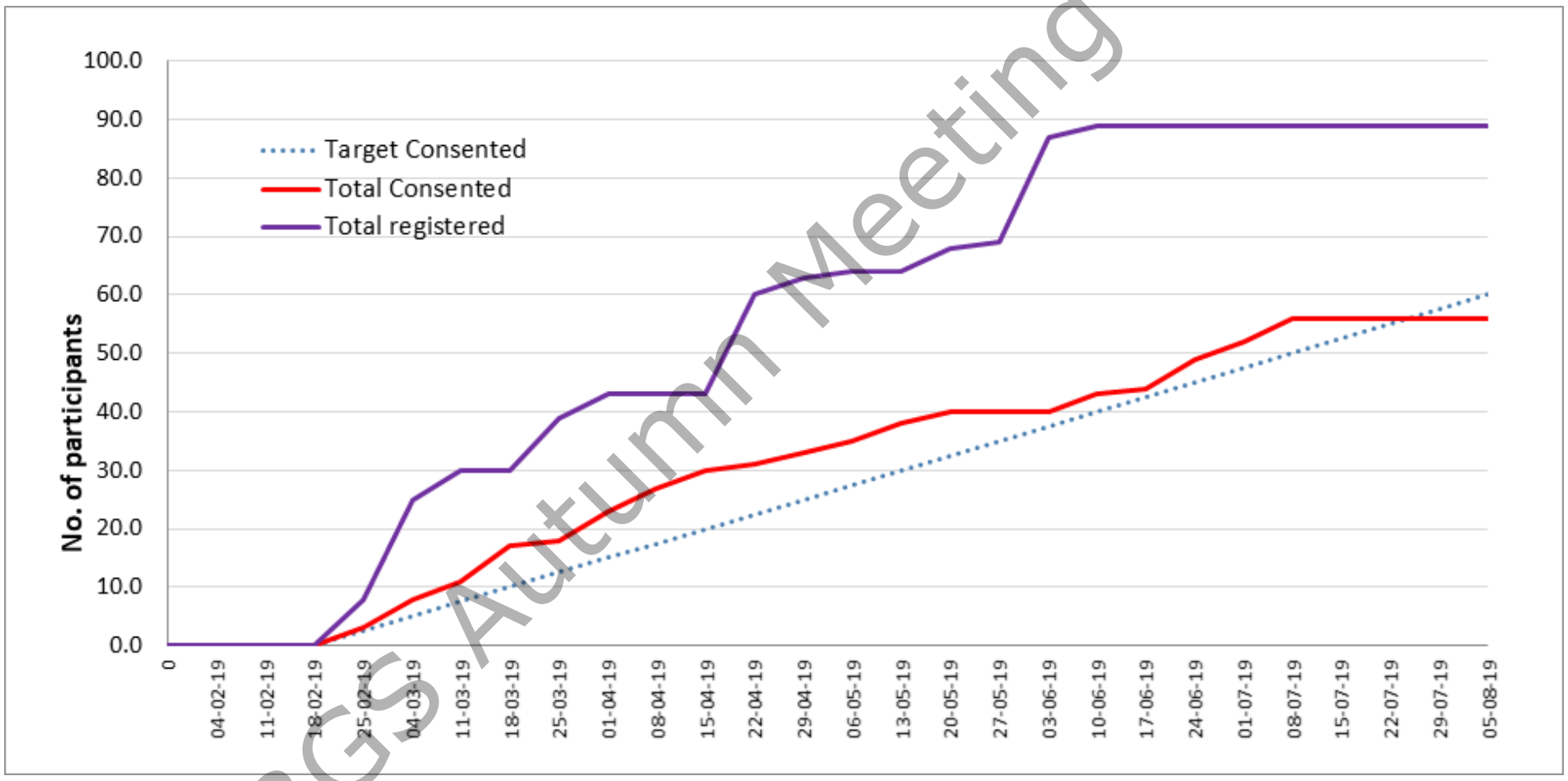
Progress to date: Recruitment



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Progress to date: Feasibility

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- Capacity to undertake initial participant identification and eligibility procedures
- Fidelity to protocol: lack of research knowledge and experience at sites
- Communication between some sites and the Chief Investigator (CI) has proved challenging
- Unexpected community matron capacity issues

However……

Recruitment has proved relatively easy with participants keen to be involved

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Acknowledgements

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Sites
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All HAPPI Study Participants

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Thank you for your attention. Any questions?

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