

# THE HAPPI STUDY

## Trial Steering Group Update



## OPEN FOR RECRUITMENT

The HAPPI study was given sponsor green light on 1<sup>st</sup> December 2018 and is now open to recruitment. This means that the practices (sites) have begun the screening and eligibility process.

### Study contacts:

[helen.lyndon@plymouth.ac.uk](mailto:helen.lyndon@plymouth.ac.uk)

Website: <https://www.plymouth.ac.uk/research/the-holistic-assessment-and-care-planning-in-partnership-intervention-study-happi>

Twitter: @HappyStudy

### SITES PROGRESS

All Site Initiation Visits have been completed with all general practices and Cornwall Foundation Trust (CFT). The CFT Research Team have received training in study procedures. As planned the general practice sites will be started in pairs (one intervention, one control). The first sites to start are the Clays Practice and the Alverton Practice. Both practices have completed screening, sampling and eligibility and have sent out recruitment letters.

The next two sites to start screening, sampling and eligibility are St Austell Healthcare and The Roseland Practice. Both practices have provided initial eFI lists which have been sampled. They are in the process of applying eligibility criteria.

The final two sites will commence on 1<sup>st</sup> March 2019 and will be Carn to Coast Health Centres and Three Spires Medical Practice.

### Randomisation

A randomisation specification was developed in December 2018 and approved by the Trial Steering Committee Statistician. Randomisation of the general practice sites happened shortly after.

### Trial Database

All study documentation is now complete including all case report forms and outcome questionnaires. The trial database has been developed by PenCTU and is now complete and live. The database will be used to capture and analyse all data and provide reports.

### Community Matron Training

Training on delivery of the intervention and study procedures has been delivered to two-thirds of the community matrons involved with a final training session planned for 7<sup>th</sup> March.

### Study Communications/Publications

The study now has a Twitter account, please follow us on @HappyStudy. The website has been updated with trial documentation and a progress report. When the study opened for recruitment the NIHR Clinical Research Network South West Peninsula issued a press release and Helen Lyndon gave an interview on Radio Cornwall to raise awareness of the study. Journal articles are planned including the a summary of the patient and public involvement consultation and the study protocol, to be submitted to the Journal of Advanced Nursing for publication.

### Study Timelines

Currently, we remain on track against the proposed timeline. There was a month delay in obtaining sponsor green light due to delays in finalising agreements with all practices. There have been some delays in obtaining screening information from the initial practices which was worsened by the Christmas/New Year break and challenges for some including premises move and closure of neighbouring practices causing an increase in workload. It is hoped that now initial procedures have been tested and refined then any delays can be mitigated in the later practices and the study will remain on track.