The Community Navigator Trial
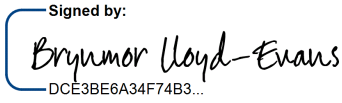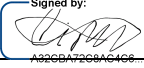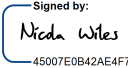
HEALTH ECONOMIC ANALYSIS PLAN (HEAP)

Version	Date	Changes	Changes made by:
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1. AIM

The primary aim of the health economic analysis is to calculate the mean incremental cost per quality adjusted life year (QALY) gained of Community Navigators plus usual care compared to usual care over 14 months from health and social care cost perspective. The primary analysis will use QALYs derived from the EQ-5D-5L, and a secondary analysis will use QALYs derived from the Recovering Quality of Life (ReQoL). A further secondary analysis, from a wider cost perspective, including productivity and absenteeism and the cost of voluntary services, will also be conducted using QALYs derived from the EQ-5D-5L and ReQoL.

The health economic analysis will follow the statistical analysis plan (SAP v1.0). All analyses will be intention-to-treat (ITT) where all randomised patients are analysed in their allocated group whether or not they received their allocated treatment.

2. OUTCOMES

A full description of all outcomes and analysis are provided in the SAP and Trial Protocol. The following outcomes will be used for the within-trial economic evaluation:

- Participants' mental health service use will be collected from health records, including contact with mental health staff and any use of inpatient or crisis service.

- A modified client services receipt inventory (CSRI) [1] will be completed by participants with researcher support collecting information on health and social care use (other than mental health) at baseline, 8 and 14 months asking about the last 6 months. Whilst this does result in missing some resource use in the first 2 months, 6 months is generally agreed to be the maximum recall period recommended to minimise the risk of errors due to patient recall [2]. The CSRI will also collect information on employment status, employed participants' time of work in the last 6 months and accommodation, for the wider societal costs analysis.

- A bespoke daily activities questionnaire to be completed by the participants at baseline, 4, 8, 11 and 14 months. It will collect information on the use of social prescribing schemes, befriending, peer support groups and other social clubs, organisation and voluntary sector groups at baseline and each follow-up time-point to collect detailed information on any additional activities that might have occurred

as a result of the intervention, with equivalent information also collected for the group receiving only usual care. This questionnaire is shorter than the CSRI allowing us to collect it at an additional 4-month timepoint to balance missing information on resource use and patient burden.

- Work Productivity and Impairment Questionnaire – General Health (WPAI-GH) [3] collected within the CSRI at baseline, 8 and 14 months will be used to capture information on absenteeism and presenteeism.
- EQ-5D-5L [4] at baseline, 8 and 14 months to calculate utility for cost per QALY analysis.
- Recovering Quality of Life-10 (ReQoL-10) [5] at baseline, 8 and 14 months to calculate utility for the secondary cost per QALY analysis.

3. COST DATA

Cost of the CN Intervention
We will calculate the cost of delivering the Community Navigator intervention, including training and supervision based on activity reported by the community navigators. Unit costs for staff costs and Community Navigator costs will be taken from the most recent version of the Personal Social Services Resource Unit (PSSRU)'s unit costs of health and social care [6].

Physical and mental health service resource use
Descriptive statistics for the percentage of patients and mean number of contacts for each type of physical and mental health care resource use collected by the CSRI and health records will be reported by group at baseline, 8- and 14-months post randomisation. Information on data completeness will also be reported.

Cost of health and social care service use and medication
The cost of physical care service use for the CN versus usual care group will be calculated from participant completed CSRI and the cost of mental health care from patient records. These will be costed for each participant using unit costs from the most recent PSSRU Unit Costs of health and social care [6], reference costs [7] and other published sources where needed. Costs from previous years will be inflated to the year of publication of the most recent version

of the PSSRU and reference costs using the PSSRU hospital and community health services (HCHS) index. Medication will be costed using the most up to date version of the British National Formulary (BNF) [8]. Mean total healthcare resource use cost per patient and by type of service use for the CN versus usual care group will be reported at baseline, 8- and 14 months post randomisation.

To calculate the difference in healthcare resource use costs at 14 months between CN and usual care, costs will be adjusted by baseline values, with site included as a covariate and clustering for Community Navigator. 95% CIs will be calculated based on bootstrapped bias corrected results.

Wider societal costs

A wider societal analysis will include health and social care resource use costs as well as the cost of voluntary services, accommodation, and losses to productivity through absenteeism and presenteeism. The cost of voluntary services will be calculated from patient response to the Daily Activities questionnaire at baseline, 4-, 8-, 11- and 14-months post randomisation and will be costed using published sources. The cost of losses to productivity and absenteeism will be costed using the human capital approach based on responses to the CSRI including the WPAI-GH at baseline 8- and 14-month. These costs will be calculated using data from the Office of National Statistics (ONS) on earnings and working hours [9]. Mean wider societal cost per patient for the CN versus usual care group will be reported at baseline, 8- and 14 months post randomisation. The difference in costs at 14 months between CN and usual care will be calculated with an adjustment for baseline values, with site included as a covariate and clustering for community navigator. 95% CIs will be calculated based on bootstrapped bias corrected results.

4. QUALITY OF LIFE DATA COLLECTION

The primary measure used to calculate QALYs will be the EQ-5D-5L using (a) the EQ-5D-3L mapping function developed by Hernández Alava et al. recommended by the National Institute of Health and Care Excellence (NICE) [10] (b) the EQ-5D-5L value set [11] to derive utility values. QALYs will be calculated as the area under the curve using the EQ-5D-5L responses at baseline, 8- and 14-months post randomisation. For the CN versus usual care

group, we will report the mean utility values at each time point; mean unadjusted QALYs from baseline to 14 months; and mean QALYs adjusting for baseline using regression analysis [12]. A covariate for site will also be included in the regression analysis as well as clustering for Community Navigator. QALYs will also be calculated reported in a similar manner using responses to the ReQoL-10 at baseline, 8- and 14 months post randomisation using the subset of questions which forms the ReQoL-UI and the valuation by Keetharuth et al., to calculate utilities and QALYs [13]. 95% confidence intervals for all analyses above will be calculated from bootstrapping with bias correction.

5. PRIMARY WITHIN-TRIAL ANALYSIS

The primary economic evaluation will be a within-trial cost-effectiveness analysis over 14 months from a health and social care cost perspective.

Incremental cost-effectiveness ratio (ICER)

The primary result will be the mean incremental cost per QALY gained adjusting for baseline differences and with site as a covariate as well as clustering by CN. Costs will be bootstrap-adjusted costs as reported in section 3 and will include the cost of the CN intervention in the CN group and the cost of health and social care services in both groups. QALYs will be bootstrap-adjusted QALYs calculated using the EQ-5D-5L and the methodology described in section 4. A two-stage bootstrap will be used to account for the correlation between costs and outcomes.

Cost-effectiveness acceptability curve (CEAC) and Cost-effectiveness Plane

The bootstrap results will be used to calculate the CEAC: the probability that the CN intervention is cost-effective compared to usual care for a range of values of cost-effectiveness thresholds. A cost-effectiveness plane of the bias-corrected bootstrap results will also be reported.

6. MISSING DATA

In line with the statistical analysis plan, missing outcome data will be summarised separately by randomised group. Predictors of missingness will be investigated and used as covariates in a sensitivity analysis. Consideration regarding multiple imputation for missing data will

follow the recommendations made in Faria et al [14], stepping through more complex methods of accounting for missing data.

7. SECONDARY WITHIN-TRIAL ANALYSES

ICERs, CEACs and CEPs will be reported for the following analyses:

i) Health and social care cost perspective using the ReQoL for the calculation of QALYS.

ii) A wider cost perspective as outlined in section 3 using the EQ-5D-5L for the calculation of QALYS

iii) A wider cost perspective as outlined in section 3 using the ReQoL for the calculation of QALYS

8. DISCOUNTING

All costs and outcomes after 12 months will be discounted at a rate of 3.5% in line with NICE guidance [10].

9. SENSITIVITY ANALYSIS

In addition to the CEAC and CEP analysis described in section 5 above, one- and two-way sensitivity analyses will be used to explore the impact of key cost assumptions on the findings, particular in relation to the cost of the CN intervention.

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