**Health Economics Analysis Plan**

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**Health Economic Analysis Plan for the FinCH trial: Falls in Care Homes (FinCH)**

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**SECTION 1: ADMINISTRATIVE INFORMATION**

* 1. **Title:** Health Economic Analysis Plan for the FinCH trial: Falls in Care Homes (FinCH)
	2. **Trial registration number:** ISRCTN34353836
	3. **Source of funding:**National Institute for Health Research HTA Programme (NIHR HTA Project 13/115/29) is providing funding for research costs for the project duration to cover trial set up, trial conduct, analysis and report writing. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA programme, the NIHR, the NHS or the Department of Health.
	4. **Purpose of HEAP**This document will outline the methods to be used in the economic evaluation to be conducted alongside the FinCH Trial, including how data will be collected, analysed and reported. It will be finalised and reviewed prior to the trial database being locked to ensure it is appropriate to the aims of the trial and reflective of current practice. This HEAP has been written in line with the trial protocol and SAP in order to ensure there is consistency.

Amendments to the health economics analysis plan will be described and justified in the final report of the trial.

**1.5** **Trial protocol version**This document has been written based on information contained in the trial protocol version 6.0, dated 14th November 2017.

 **1.6 Trial statistical analysis plan (SAP) version**SAP version: 0.1, 10TH April 2019

 **1.7 Trial HEAP version**HEAP version: 0.1, Date: 14th May 2019

**1.8 HEAP revisions**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Protocol Version | Updated HEAP version No | Section number changed | Description of and reason for change | Individual making the change | Individual making the change |
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**1.9 Roles and responsibilities**This HEAP was written by the senior health economist (TS), who is a co-applicant on the grant, and Lisa Irvine (LI), the Research Fellow for the project. TS has inputted into the design of the wider trial as well as taken the lead on designing all aspects of the health economics analysis attached to the FinCH trial. TS will be advising on the economic analysis and writing up the within-trial economic. LI will undertake the within-trial analyses and contribute to and review the write-up for accuracy.

**1.10 Signature(s):**

|  |
| --- |
| The following people have reviewed the Health Economic Analysis Plan and are in agreement with its contents |
| **Name** | **Role** | **Signature**  | **Date** |
| Prof Tracey Sach | FinCH Co-investigator / CTU Health Economist  |  |  |
| Lisa Irvine | CTU Health Economist |  |  |
|  |  |  |  |
| Associate Prof Sarah Armstrong | Trial Statistician |  |  |
|  |  |  |  |
|  |  |  |  |
| Prof Pip Logan  | Chief Investigator |  |  |

**1.11Abbreviations/glossary of terms/definitions**List any abbreviations and/or acronyms used within the HEAP alongside their meanings/definitions

|  |  |
| --- | --- |
| **Abbreviation** | **Meaning** |
| CEA | Cost Effectiveness Analysis |
| CEAC | Cost Effectiveness Acceptability Curve |
| CUA | Cost Utility Analysis |
| DEMQOL- U | Dementia Quality of Life Utility version, self-complete |
| DEMQOL-P-U | Dementia Quality of Life Utility version, proxy-complete |
| EQ-5D-5L | EuroQol Five Dimensions Five Levels, self-complete |
| EQ-5D-5L-P | EuroQol Five Dimensions Five Levels, proxy-complete |
| HEAP | Health Economic Analysis Plan |
| ICER | Incremental Cost Effectiveness Ratio |
| NHS | National Health Service |
| QALY | Quality-Adjusted Life Year |

**SECTION 2: TRIAL INTRODUCTION AND BACKGROUND**

**2.1 Trial background and rationale:**

Falls in older care home residents (1.5-2.8 per year) (Rapp 2009, Whitney 2012) are at least five times more frequent than in community dwelling adults (WHO 2007) and have higher direct costs (Heinrich 2010). In care homes, nearly 1 in 10 people who fall sustain a fracture (Rapp 2009), 1 in 5 are admitted to hospital (Scuffham 2003) and 1 in 5 will die within a year (Leibson et al., 2002) due to a fall related injury. One third of the UK’s hip fractures occur in care home residents (Scuffham 2003), which is devastating to patients and their carers, and costly to the NHS. At present, hip fractures cost the NHS £1.4 billion per year with the figure set to double by 2050 (Becker 2003). An important strategy in preventing fractures, alongside improving bone health, is to prevent the falls which cause the fractures.

The Guide to Action in Care Homes (GtACH) intervention aims to reduce fall rates by facilitating change in practice of care home staff. It was co-produced by a group of care home staff, clinicians, researchers, public, voluntary and social care organisations and includes care home staff training, support and documentation. With training, the GtACH takes on average 20 minutes to complete for each resident, compared to 2 hours per resident without training (Robertson 2012). An introductory GtACH paper has been published (Robertson 2012) and its content and delivery have been refined through a proof of concept study (Robertson 2010) and a Research for Patient Benefit (RfPB) funded randomised controlled feasibility trial (Walker 2016; REC number: 12/WM/0091).

Testing the effectiveness of interventions to prevent falls and injuries in those over 65 years of age is a priority (RoSPA, 2013). The FinCH trial is a cluster randomised controlled, 2 arm, parallel group trial comparing the GtACH fall prevention intervention against usual care for people living in care homes in England (with and without nursing). Care home is the unit of randomisation.

**2.2 Aim(s) of the trial**Briefly, the FinCH trial aims to determine the clinical and cost effectiveness of the GtACH for fall prevention in care homes compared to usual care. A process evaluation will be conducted in parallel with the trial to consider whether the intervention was implemented as intended and to describe usual care.

**2.3 Objectives and/or research hypotheses of the trial**The primary objective of the FinCH trial is to compare the rate of falls per resident in the 2 trial arms (GtACH arm and usual practice control arm) during the 3 month period comprising 4,5 and 6 months post randomisation.

Secondary objectives include fall rates over later 3 month periods, frequency of fall injuries, frequency and type of fractures, physical activity, functional ability, Quality of life, Medication, number of days in hospital and number of deaths. The health economic analysis will focus on the costs and outcomes over the whole 12 months.

 **2.4 Trial population**

 **Care home inclusion criteria:**

• Long stay with old age and or dementia registration

• 10 or more potentially eligible residents

• Routinely record falls in resident personal records and on incident sheets

• Consent of care home manager to comply with the protocol and identify a care home fall champion

**Care home exclusion criteria:**

• Participated in GtACH pilot/feasibility studies

• Homes exclusively providing care for those with learning difficulties or substance dependency

• Homes with contracts under suspension with health or social providers, or that are currently subject to safeguarding investigations or homes under CQC special measures

• Homes with a significant proportion of beds taken up by health-service commissioned intermediate-care services

• Trained and routinely using a systematic falls prevention programme

**Resident eligibility criteria are:**

• All long term care home residents providing informed consent

• Residents without capacity to provide informed consent must have a relative/consultee who will provide advice on their behalf

**Resident exclusion criteria**

• Residents in receipt of end of life care or in the home for short term care, respite care or for rehabilitation

**2.5 Intervention and comparator(s)**Intervention: The specific technology under investigation is the Guide to Action Care Home (GtACH) fall prevention programme, delivered to care home residents by care home staff who have been trained and are supported (Walker 2016, Robertson et al 2010 and 2012). GtACH is a systematic falls risk assessment and action process, co-designed by care home and NHS staff, based on NICE clinical guidelines. The assessment takes 15 minutes and actions take up to 2 hours per resident.

Control: The comparator to the intervention will be usual care, where usual care is defined as the absence of a systematic and coordinated falls prevention process. The control care homes will have the option to receive the GTACH training at the end of the trial.

**2.6 Trial design**FinCH is a cluster randomised controlled with 2 arm parallel group trial design comparing the GtACH fall prevention intervention against usual care for people living in care homes in England (with and without nursing). The unit of randomisation is the Care Home.

**2.7 Trial start and end dates**Recruitment of care homes started in November 2016 and finished in December 2017, but with some randomised in January 2018. The follow up period will run until early February 2019.

Full details of the trial are given in the protocol.

**SECTION 3: ECONOMIC APPROACH/OVERVIEW**

**3.1 Aim(s) of economic evaluation**The aim of the economic evaluation is to address the question "What is the cost-effectiveness of The Guide to Action in Care Homes (GtACH) intervention compared to usual care (an absence of a systematic and coordinated falls prevention process) in UK care homes from an NHS and PSS perspective over the trial duration"?

**3.2 Objectives(s)/hypotheses of economic evaluation**The primary objective of the within trial economic evaluation is to estimate the cost-effectiveness of The Guide to Action in Care Homes (GtACH) intervention compared to usual care in UK care homes from an NHS and PSS perspective over 12 months.

**3.3 Overview of economic analysis**The Base case within-trial economic analysis will use individual resident level data collected over 12 months from the FinCH trial. The base case analysis will undertake a cost utility analysis from an NHS and PSS perspective estimating the incremental cost per QALY (as estimated using the DEMQOL-P-U) calculated by taking the ratio of the difference in the mean costs and mean effects. Two secondary analyses will be undertaken. Cost-utility will be re-estimated using utility estimated using the EQ-5D-5L proxy to estimate QALYS and for those residents with data available (due to mental capacity) the EQ-5D and DEMQOL-U self-complete. This secondary analysis is important due to uncertainties about how best to capture health utilities in this population (Rowen et al. 2012, Mulhern et al 2013, Herdman et al 2011).

The evaluation will adhere to published guidelines for the economic evaluation of health care interventions as appropriate (Drummond et al 2015; Ramsey et al 2015; Glick et al 2014; Husereau, D., 2013, NICE 2013).

**3.4 Jurisdiction**The trial is being conducted in the UK which has a national health service (NHS), providing publicly funded healthcare which is largely free of charge at the point of use. Care home provision and Personal social services have mixed funding depending on ability to pay.

**3.5 Perspective(s)**The analysis will take an NHS and PSS perspective in keeping with the NICE reference case (NICE 2013). All NHS and PSS resource use will be collected, not only that specific to falls.

**3.6 Time horizon**The primary economic analysis will compare the costs and consequences of each arm over the first 12 month after randomisation.

**SECTION 4: ECONOMIC DATA COLLECTION AND MANAGEMENT**

**4.1 Statistical software used for HE analysis**STATA MP 15.1 will be used to conduct the analysis.

**4.2 Identification of resources**Identification of relevant health care and social care resources will be ascertained at an early stage by the trial health economists and in consultation with the clinical team. Items for costing will be identified from the pilot study (Fich), literature searches, and referring to the Database of Instruments for Resource Use (DIRUM [www.dirum.org](http://www.dirum.org)). The cost analysis will focus on high cost drivers and those resources which are expected to differ between study arms (Ramsey et al., 2005).

Resource use data will be collected from a variety of sources as detailed below:

Intervention resource use

Intervention costs belong in two categories – those that are fixed costs (i.e. incurred at the beginning no matter how many residents are recruited) and those that are variable and depend on how many residents participate.

The fixed costs include the GtACH documentation, the GtACH training session which is to be delivered to at least 80% of care home staff by the site falls lead, the GtACH refresher training and support provided by the falls prevention leads in the first 3 months of delivery. Specific training details will be recorded by the Falls Lead at each site and multiple responses will be collated and an average annualised unit cost estimated. If costs vary widely between centres or individual falls leads, sensitivity analysis may be performed.

The variable costs of the intervention will be captured in the trial case report form (CRF) for each resident recording health and social care resource use items directly related to the intervention, including time spent undertaking the risk assessment, implementing the GtACH plan and adaptive equipment ordered as a result of the intervention (the equipment cost will be annualised to reflect the expected lifespan of the piece of equipment). Over the 12 month period any re-assessments using the GtACH, due to for instance a fall being experienced, will be captured.

Resource use associated with wider health and social care contacts

Routinely collected data will be obtained from the following record source by the research assistants at each care home:

Care home records (to collect data on falls, fractures, use of aids, health and social care service use, referral to secondary care, death).

Incident report forms (alternative source of data on falls)

Medication administration record (consent will be sought to allow clarification of medication data from GP records where necessary)

Hospital episode statistics (to collect data on inpatient admission, outpatient, and A&E visits sourced via NHS digital)

**4.3 Measurement of resource use data**Baseline resource use will be collected as it is likely to predict future costs. This will monitor resource use three months prior to randomisation.

Resource use will be extracted from care home residents care plans by study research associates at baseline, and 3, 6, 9, and 12 month follow-up. Researchers will complete the extraction at the care home and enter the data directly to the study-specific website. This data collection method was piloted at a sample of care homes as part of the FiCH feasibility study.

**4.4 Valuation of resource use data**All resource use will be valued in monetary terms using appropriate UK unit costs estimated for the most up to date cost year at the time of analysis.

Unit costs for the most recent year available will be applied based on annually published national sources such as National Schedule of Reference Costs, the PSSRU’s Unit Costs of Health and Social Care, and the Prescription cost analysis (DH 2018, Curtis and Burns 2018, HSCIC 2018). If national costs do not exist for items of resource use, unit costs will be sourced locally or from published peer review journals. To ensure transparency and reproducibility, a table showing the main resource items, their costs and sources will be reported (See Appendix 1).

**4.5 Identification of outcome(s)**The economic evaluation includes a generic outcome measure, EuroQol EQ-5D-5L and a dementia-specific outcome measure, the DEMQOL-U (Mulhern 2013, Rowen et al., 2012) both of which can be used to estimate Quality Adjusted Life Years (QALYs). Both have self-complete and proxy versions available, thus with concerns about poor reliability (Devine 2013) this trial will collect proxy estimates for all residents from their main carer. Those with capacity will be asked to self-report quality of life measures. We will then be able to compare likely bias. The feasibility study showed that residents with capacity were accepting towards completion of a relative self-report measure; the Barthel ADL (Collin 1988) and care staff were accepting of proxy completion.

The choice to use both instruments reflects the fact that the utility value sets, DEMQOL-U and DEMQOL-P-U, have only recently been published so have not been extensively used or validated as yet in funded trials. We are aware from previous research that measuring HRQL in care home populations can be problematic in terms of achieving good response rates due to high cognitive impairment (Gordon et al., 2010), however, the EQ-5D-5L has successfully been used in a care home population to inform the economic evaluation of exercise for depression (Underwood 2013).

The primary base case analysis will use the DEMQOL-P-U to estimates QALYs. Secondary analyses will consider the other utility alternatives. A further secondary analysis will undertake a cost effectiveness analysis reporting the incremental cost per fall prevented over the 12 months.

**4.6 Measurement of outcome(s)**Residents or their proxy will complete outcomes questionnaires at baseline and at 3, 6, 9 and 12 months follow-up.

**4.7 Valuation of outcome(s)**In the cost utility analysis, the responses received on the quality of life instruments will be converted to utility scores, the DEMQOL-P-U and DEMQOL-U using the valuation set published by Mulhern et al 2013 and Rowen et al 2012. Utility as captured on the EQ-5D-5L will be estimated using UK preference weights in line with current recommendations at the time of the analysis (NICE 2017; Devlin et al 2016). Following this, the utility values will be used to calculate the number of quality adjusted life years (QALYs) generated over the trial period of 12 months, using both linear interpolation and area under the curve analysis with and without baseline adjustment (Manca, 2005).

A secondary cost effectiveness analysis will be undertaken to report the cost per fall prevented over the 12 month trial period.

**SECTION 5: ECONOMIC DATA ANALYSIS**

**5.1 Analysis population**The economic base-case analysis will take an intention to treat principle approach including all randomised residents with data available. The final number of residents included in the economic analysis will be stated, as this may be different from the primary clinical analysis. Since data on resource use and utility is collected from care home notes review and proxy completed residents who die during the course of the study will be included in the analysis to reflect the fact that the intervention may have an impact on rate of death.

**5.2 Timing of analyses**The primary final analysis will be a within-trial analysis conducted once all residents have been followed for 12 months after GtACH training has taken place. The data will be cleaned and locked before analysis begins.

**5.3 Discount rates for costs and benefits**As the trial is only for one year of resident follow-up, costs and outcomes will not be subject to discounting.

**5.4 Cost-effectiveness threshold(s)**The estimated mean costs and QALYs per resident associated with each intervention option will be combined with a feasible range of values for decision makers' willingness to pay (ʎ), to obtain a distribution of net benefits at different levels of ʎ. The economic analysis will use a cost-effectiveness threshold (ʎ) of £20,000 per QALY.

**5.5 Statistical decision rule(s)**As appropriate, all statistical tests will be two-sided with the statistical significance level set at 5%.

**5.6 Analysis of resource Use**Mean (sd) resource use per resident will be estimated for each randomised group. Mean difference (95% CI) in resource use per resident between arms will be presented.

**5.7 Analysis of costs**Mean (sd) cost per resident will be estimated for each randomised group. Mean difference (95% CI) in cost per resident between arms will be estimated unadjusted and adjusted (for for type of care home (residential, nursing, dual registration), site, and any other variable deemed appropriate, for instance baseline cost).

The primary analysis will include residents who died during the study. We will report separately the mean cost at each time point, the mean cost per intervention arm and mean (95% CI) difference in cost over the 12 month period excluding those who died during the study for comparison.

**5.8 Analysis of outcomes**The primary outcome for the economic evaluation will be quality-adjusted life years (QALYs) of the resident at 12 months as valued using the DEMOQOL-P-U. Utility values will be obtained from the proxies and individuals' own (where they have mental capacity) health related quality of life responses to the DEMQOL-U and EQ-5D-5L questionnaire at baseline, 3, 6, 9 and 12 months. Responses will be converted into a utility using standard UK tariff values, the DEMQOL-P-U and DEMQOL-U using the valuation set published by Mulhern et al 2013 and Rowen et al 2012 and those for the EQ-5D-5L in line with recommendations at the time of analysis (NICE 2017; Devlin et al 2016) . These utilities will represent patients' overall quality of life and be multiplied by the time spent in each state to generate QALYs. Qalys will be estimated unadjusted and adjusted (Manca, 2005) using an appropriate regression model to adjust for any imbalance in baseline utility (however small) and the type of care home and site. These will be presented as mean (SD) utility and mean (sd) QALYS per resident per randomised group and mean difference (95% CI) in utility and QALYs between arms will be estimated unadjusted and adjusted (for centre and number of immediate family members with atopic disease (1, 2 or more than 2)).

The primary analysis will include residents who died during the study. We will report separately the mean utility at each time point, the mean QALY per intervention arm and mean (95% CI) difference in QALY over the 12 month period excluding those who died during the study for comparison.

**5.9 Data Cleaning for analysis**

Before carrying out analyses, plausibility checks will be performed on the relevant data fields, such as resource use and reported outcome measures, such as quality of life. Where problems are identified, the health economist will contact the data manager of the trial for clarification.

**5.10 Missing data**The economic analysis will examine the data for any missing data. Since resource use data is being collected from notes review and utility instruments are proxy completed this data should be available for all residents up to the point where they died or the study finished. Those that died during the study have censored data but will be included in the analysis using the data available until death. Those that died will only contribute to the rate of missing data where data is missing for the period whilst they were alive. If the share of missing data is less than 10% a complete case analysis will be undertaken as part of the base case analysis. If greater than 10% then the base case analysis will be undertaken using multiple Imputation (Faria et al 2004) assuming data are missing at random with sensitivity analysis conducting complete case analysis for comparison.

**5.11 Analysis of cost-effectiveness**

Mean cost and QALY data will be combined to calculate an incremental cost-effectiveness ratio (ICER) and net monetary benefit (NMB) statistic from the NHS and PSS perspective. Since this economic evaluation will be undertaken alongside a cluster randomised trial the analysis needs to reflect the increased uncertainty of randomising clusters rather than individuals. A number of approaches have been proposed for this, with each found to generate similar findings (Gomes 2012b, Gomes 2012a). Regression analysis of cost and QALYs, will be undertaken to adjust for important covariates as deemed appropriate (for instance, baseline cost and baseline utility).

**5.12 Sampling uncertainty**It is likely that costs and outcomes will be skewed, therefore non-parametric bootstrapping will be used to determine the level of sampling uncertainty surrounding the mean ICERs by generating 10,000 estimate of incremental costs and benefits. These estimates will be plotted on a cost-effectiveness plane. In addition, Cost-Effectiveness Acceptability Curves will be produced, which will show the probability that each of the intervention arms is cost effective at different values of willingness to pay.

**5.13 Subgroup analysis/Analysis of heterogeneity**No subgroup analyses are planned.

**5.14 Sensitivity analyses**Sensitivity analyses will be undertaken to explore uncertainties surrounding key parameters in the economic evaluation in order to investigate how robust the findings are. The following sensitivity analyses will be undertaken if appropriate:

1. Dealing with missing data, see section 5.10.
2. The cost of the GtACH intervention will be varied to test the impact this has on the incremental cost per QALY estimated using the DEMQOL-P-U. Values will be varied to find at what cost, if any, the intervention would switch from being cost effective to cost ineffective or vice versa.

Additional analyses using the health economic data beyond that described in this document may be possible, in particular, further work could be undertaken to compare the performance of the EQ-5D-5L and DEMQOL-U as well as a using the HES data (subject to approvals) to estimate the cost of a fall. This work will not be reported within the NIHR Journals monograph.

**SECTION 6: MODELLING AND VALUE OF INFORMATION ANALYSES**

**6.1 Extrapolation or Decision analytic modelling**The within-trial base case time horizon will be 12 months. It is expected that the majority of costs and benefits associated with the intervention will be captured in this period, and therefore it is not considered necessary to develop a decision-analytic model.

**SECTION 7: REPORTING/PUBLISHING**

The economic analysis will be published alongside the clinical analysis in a peer-reviewed journal as appropriate.

**7.1 Reporting standards**The CHEERS reporting quality guidelines will be followed when writing up the health economic evaluation (Husereau et al 2013).

**7.2 Reporting deviations from the HEAP**Any deviations necessary from the HEAP will be described and justified in the main study report (NIHR HTA monograph).

**SECTION 8: Appendices**

 **8.1 Appendices: Example Tables**

**Unit Costs Table (UK£ sterling, Price Year)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Cost Item** | **Unit of measure** | **Unit Cost (£)** | **Source** |
| **Intervention** |  |  |  |
| Development |  |  |  |
| Delivery |  |  |  |
| **NHS Care** |  |  |  |
| GP (in hours) | Appointment / telephone call / home visit |  | PSSRU |
| GP (out of hours) | telephone call / home visit |  | PSSRU |
| Practice Nurse | Appointment / telephone call / home visit |  | PSSRU |
| District Nurse | Appointment / telephone call / home visit |  | PSSRU |
| Physiotherapist | Per appointment |  | PSSRU |
| Occupational Therapist | Per appointment |  | PSSRU |
| Chiropodist/Podiatrist | Per appointment |  | PSSRU |
| Social worker | Per appointment |  | PSSRU |
| Pharmacist | Per appointment |  | PSSRU |
| Inpatient stay | Bed day |  | NHS Reference costs |
| Tests or procedures | Per test |  | NHS Reference costs |
| Other (incl. secondary care not covered above) |  |  |  |
| **Prescribed medication** | Per item |  | Prescription cost analysis |

**Mean (sd) resource use and mean (95% CI) difference in resource use at 24 months**

|  |  |  |  |
| --- | --- | --- | --- |
| **Cost Item** | **GtACH Intervention (n=)** | **Usual care (n=)** | **Mean difference (95% CI)** |
| **Intervention** |  |  |  |
| Development |  |  |  |
| Delivery |  |  |  |
| **NHS Care** |  |  |  |
| GP (in hours) |  |  |  |
| GP (out of hours) |  |  |  |
| Practice Nurse |  |  |  |
| District Nurse |  |  |  |
| Physiotherapist |  |  |  |
| Occupational Therapist |  |  |  |
| Chiropodist/Podiatrist |  |  |  |
| Social worker |  |  |  |
| Pharmacist |  |  |  |
| Inpatient stay |  |  |  |
| Tests or procedures |  |  |  |
| Other (incl. secondary care not covered above) |  |  |  |
| **Prescribed medication** |  |  |  |

**Mean (sd) cost and mean difference in cost at 24 months**

|  |  |  |  |
| --- | --- | --- | --- |
| **Cost Item** | **GtACH Intervention (n=)** | **Usual care (n=)** | **Mean difference (95% CI)** |
| **Intervention** |  |  |  |
| Development |  |  |  |
| Delivery |  |  |  |
| **NHS Care** |  |  |  |
| GP (in hours) |  |  |  |
| GP (out of hours) |  |  |  |
| Practice Nurse |  |  |  |
| District Nurse |  |  |  |
| Physiotherapist |  |  |  |
| Occupational Therapist |  |  |  |
| Chiropodist/Podiatrist |  |  |  |
| Social worker |  |  |  |
| Pharmacist |  |  |  |
| Inpatient stay |  |  |  |
| Tests or procedures |  |  |  |
| Other (incl. secondary care not covered above) |  |  |  |
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|  |  |  |  |
| **Prescribed medication** |  |  |  |

**Utility and QALYs**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **GtACH Intervention (n=)** | **Usual Care (n=)** |  |
|  | **Mean** | **Std dev** | **Mean** | **Std dev** | **n** |
| **Proxy Completed**  |  |
| DEMQOL-P-U baseline |  |  |  |  |  |
| DEMQOL-P-U 3 months |  |  |  |  |  |
| DEMQOL-P-U 6 months |  |  |  |  |  |
| DEMQOL-P-U 9 months |  |  |  |  |  |
| DEMQOL-P-U 12 months |  |  |  |  |  |
| QALYs (DEMQOL-P-U) at 12 months |  |  |  |  |  |
| EQ-5D-5L-P baseline |  |  |  |  |  |
| EQ-5D-5L-P 3 months |  |  |  |  |  |
| EQ-5D-5L-P 6 months |  |  |  |  |  |
| EQ-5D-5L-P 9 months |  |  |  |  |  |
| EQ-5D-5L-P 12 months |  |  |  |  |  |
| QALYs (EQ-5D-5L-P) at 12 months |  |  |  |  |  |
| **Self-completed**  |  |
| DEMQOL-U baseline |  |  |  |  |  |
| DEMQOL-U 3 months |  |  |  |  |  |
| DEMQOL-U 6 months |  |  |  |  |  |
| DEMQOL-U 9 months |  |  |  |  |  |
| DEMQOL-U 12 months |  |  |  |  |  |
| QALYs (DEMQOL-U) at 12 months |  |  |  |  |  |
| EQ-5D-5L baseline |  |  |  |  |  |
| EQ-5D-5L 3 months |  |  |  |  |  |
| EQ-5D-5L 6 months |  |  |  |  |  |
| EQ-5D-5L 9 months |  |  |  |  |  |
| EQ-5D-5L 12 months |  |  |  |  |  |
| QALYs (EQ-5D-5L) at 12 months |  |  |  |  |  |

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