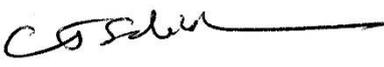


The 3D Study: Improving whole person care

Health Economics Analysis Plan

Version 1.0 (18th May 2017)

The following people have reviewed the Health Economics Analysis Plan and are in agreement with the contents:

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1. Health Economics Analysis Plan

1.1 Purpose of plan

The purpose of this health economics analysis plan is to set out in detail the analysis and reporting procedure intended for the economic analyses to be undertaken in the 3D trial. While the intentions outlined in this plan will be followed as closely as possible, the plan also describes the circumstances under which amendments are permitted and the documentation of such changes; any deviations from this plan will be justified in the final report. The analysis plan is designed to ensure that there is no conflict with the protocol and preceding statistical analysis plan (SAP) and should be read in conjunction with them.

1.2 Economic analysis background

Aim

The aim is to determine the cost-effectiveness of delivering a complex primary-care based intervention designed to improve management of care for multimorbid patients, compared with usual care for managing multimorbid patients.

Perspective

The primary economic analysis will be from the NHS and personal social services (PSS) perspective. A secondary analysis will be from the perspective of patients and carers (including personal travel costs, expenditure on private health care, therapies, and over-the-counter medication). We will also consider the societal cost of time off work to attend healthcare appointments.

Time horizon

The economic analysis will compare the costs and benefits of each arm over 15 months of follow-up.

1.3 Economic measurements

Identification of outcomes

The primary economic outcome measure will be Quality Adjusted Life Years (QALYs) derived from utility scores, obtained using the EQ-5D-5L quality of life instrument [1];

Measurement of outcomes

Measurements will be recorded at baseline, 9 months and 15 months post-recruitment. The instrument will be distributed and returned by post at all three timepoints. At baseline, one postal and one telephone reminder may be given. At 9 months and 15 months follow-up, patients will receive one postal and one telephone/email reminder, and EQ-5D data may be collected by telephone. Alternative completion methods including collecting the whole questionnaire by phone or via a home visit will be offered in order to maximise response rates.

Secondary outcome measures will be collected at baseline and 9 and 15 months post-recruitment from questionnaires. These measures are described in the statistical analysis plan.

Valuation of outcomes

Utility scores will be derived from responses to the EQ-5D-5L using valuations obtained from an English population [2]. These will be used to form Quality Adjusted Life Years (QALYs) over the 15-month period, adjusting for any imbalances in baseline scores [3]. Patients who have died will be treated as if their last-measured utility score was relevant until death, and immediately set to zero at death.

Identification of relevant resource use

Data will be collected for resource use related to any health condition experienced by the patient. For the NHS and PSS perspective, data will be collected on use of health services in primary and community care, investigations and prescribed medication, hospital admission and outpatient attendance, ambulance use, and social care. For the analysis from the patient/carer perspective, we will additionally collect data on travel costs and expenditure on over-the-counter medication, and private therapies and treatments. The value of productivity losses will be estimated using data on time off work by patients and carers to attend primary and secondary care appointments.

Measurement of resource use

Setup costs

Study records of the number/role attending each session will be used to track resources used in the delivery of the training programmes for GPs, nurses and receptionists, including trainee and trainer time (and preparation time), travel costs, attendance incentives and course materials to calculate the fixed cost of training. Study records will also be used to track payments made to practices relating to intervention setup (but excluding trial-related setup costs).

Delivery of intervention

For the delivery of the 3D appointments, named GP and named nurse appointments will be captured through electronic downloads of GP records, including session lengths; manual data capture may be used as a back-up if GP records do not adequately identify the 3D appointments. The number of pharmacist reviews undertaken will be recorded in trial records.

Health and social care utilisation

NHS secondary care data from the Commissioning Support Units (CSU) for the three centres will be used if available. In the absence of usable CSU data, data extracted from GP records or data from patient-reported questionnaires will be used.

NHS community care, care from social services and patient personal resource use during the 15 month follow-up will be captured using patient-reported questionnaires at 9 and 15 months (see appendices 2 and 3), administered by post. Patients will be reminded by post and then by telephone or email if the questionnaire has not been received. Additional details about secondary care will be extracted from GP records. Medications, tests/investigations and primary care contacts will be extracted from electronic downloads of routine GP records.

Transport

The patient's normal transport method for GP appointments and the cost (for public transport) or mileage (for private transport) to use as a multiplier for calculating costs will be collected in a patient-reported questionnaire at baseline (appendix 1)

Productivity

Time off work by patients and carers to attend hospital appointments will be captured in the patient-reported questionnaires at 9 and 15 months (appendices 2 and 3). Usual practice with regards to time off work for GP appointments will be recorded at baseline (appendix 1).

Personal expenditure on healthcare

Expenditure on over-the-counter medication, and private use of treatments and therapies will be captured in the patient-reported questionnaires at 9 and 15 months (appendices 2 and 3).

Valuation of resource use

Unit costs for NHS staff time to train for and deliver the intervention will be based on the most recently available national estimates (*e.g.* Curtis [4]). Actual expenses incurred for training materials, refreshments and staff travel will be recorded. The costs of medications will be estimated from the British National Formulary [5]. Community and primary care costs will be based on national estimates [4]. Codes for Healthcare Resource Groups (groups of events that have been judged to consume similar levels of resources) will be assigned to secondary care contacts and will be costed based on the most recently published national reference costs where available (*e.g.* DOH [6]), supplemented by micro-costing or local estimates if necessary. Productivity costs will be estimated based on average weekly earnings stratified by age group (*e.g.* ONS [7]). Resource use will be combined with unit costs to estimate the incremental cost or savings of the 3D intervention.

All costs will be reported in 2015/2016 pounds sterling, adjusted for inflation if necessary. Costs and outcomes occurring during the final three months of follow up will be discounted in line with NICE guidance (currently 3.5%) [8]. Owing to the extension of the final follow up from 12 to 15 months, dates may not be available for all resource-use events; dates will be estimated under these circumstances.

The cost of each resource item will be calculated by multiplying the number of resource units used by the unit cost. The total cost for each individual patient will then be estimated as the sum of the cost of resource-use items consumed.

1.4 Economic analyses

The primary (NHS and PSS) and secondary (patient/carer) cost–utility analyses will follow the same analysis plan unless mentioned otherwise. All analyses will be conducted using intention-to-treat principles, comparing the two groups as randomised and including all patients in the analysis wherever practical. The costs of each component of the intervention will also be estimated separately from each perspective and related to changes in a range of secondary outcomes in a cost–consequences analysis.

Data cleaning and missing costs and outcomes

Data cleaning and imputation will be undertaken prior to unblinding by the economic researcher. Data cleaning will include correction of obvious 'free text' response errors (*e.g.* misspelt clinic names), group coding of similar resource items (*e.g.* 'orthopaedics' and 'trauma & orthopaedics' clinics) to enable unit costing, and simple imputation of data missing minor details (*e.g.* missing drug dose) based on reasonable assumptions (*e.g.* the most commonly prescribed dose). Any areas of uncertainty will be discussed between two health economists and, where necessary, referred for adjudication by a clinical expert. The number of uninterpretable responses (*e.g.* illegible clinic names) will be reported and not included in the cost analysis. However, questionnaires will not be classed as 'missing data' for the cost analysis, unless the questionnaire is not returned or the majority of responses are uninterpretable.

The primary analysis will include all participants using imputation to predict missing costs and outcomes [9]. Data imputed for the statistical analysis will be used. The imputation models will include all cost measurements, trial arm, age, sex, GP practice (to account for clustering) and baseline EQ-5D score. If possible the same imputation models will be used for the primary analysis and the economic evaluation. The implications of the clustered design of the trial for MI will be examined and appropriate methods explored. [10, 11]

Analysis of outcomes

We will report the incremental mean difference in QALYs between the two arms of the trial and 95% confidence intervals.

Analysis of costs

Overall mean costs, stratified by NHS & PSS, patient and productivity costs, and standard deviations for both arms of the trial will be calculated. We will estimate the incremental mean difference in total costs between the two arms of the trial and 95% confidence intervals. Bootstrapping techniques will be used to derive confidence intervals [12].

Analysis of relative costs and outcomes

Cost and QALY data will be combined to calculate an incremental cost-effectiveness ratio (ICER) and net monetary benefit (NMB) statistic [13] from the NHS and PSS perspective.

$$\text{NMB}_i = \lambda E_i - C_i$$

For each individual i , the NMB statistic is given as the societal willingness to pay for a QALY, λ , multiplied by the patient outcome E_i (*i.e.* QALYs), from which the total cost C_i is subtracted. In the primary analysis we will estimate whether the 3D intervention is cost-effective at the established NICE threshold of £20,000 per QALY gained.

Uncertainty in the point estimate of cost per QALY will be quantified using bootstrapping methods to calculate confidence intervals around the ICER and NMB. The probability that the 3D intervention is cost-effective at various 'willingness to pay for a QALY' thresholds will be depicted using a cost-effectiveness acceptability curve .

A cost-consequences analysis will be presented from the NHS and PSS perspective, the patient/carer perspective and the societal productivity perspective for each arm. Consequences will include QALYs, all secondary outcomes listed in section 1.4 and deaths.

1.5 Further economic analyses

Sensitivity analyses

One way sensitivity analyses will be used to judge the potential impact of sources of uncertainty.

- Complete case analysis
- An analysis without discounting either costs or outcomes

- As there is an imbalance between arms in the number of deaths, a sensitivity analysis excluding people who have died will also be conducted.

1.6 Updating the economic analysis plan

Changes to existing analyses

Dated changes to the analysis plan will be documented in this section. Circumstances under which changes will be permitted are as follows.

- Development of novel statistical methods that are deemed more appropriate for this analysis.
- Clarification of currently debated issues.
- Preliminary data cleaning or analysis (conducted prior to unblinding) suggesting that planned analyses are sub-optimal.

Post hoc analyses

Any suitable analyses that are identified after unblinding or during the refereeing process will be listed in this section, dated and the source will be identified. Such analyses will be identified clearly as *post hoc* analyses in trial reports.

References

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Appendix 1. Resource-use information collected at baseline.

SECTION 7: YOUR CARE

7.1 Is there one doctor you prefer to see at your GP surgery or health centre?

No ₀ Yes ₁

7.2 How often do you see the doctor you prefer to see at your GP surgery or health centre?

Always or almost always ₁ A lot of the time ₂ Some of the time ₃
Never or almost never ₄ Not tried ₅ Not applicable ₆

7.3 Who do you see most often in connection with your long-term conditions?

Please tick one box

GP	<input type="checkbox"/> ₁	Practice Nurse	<input type="checkbox"/> ₂	Community Matron	<input type="checkbox"/> ₃
Hospital Doctor	<input type="checkbox"/> ₄	Hospital Nurse	<input type="checkbox"/> ₅	Other	<input type="checkbox"/> ₆

7.4 Do you have a written care plan, health plan or treatment plan?

No ₀ Yes ₁ Don't Know ₂

7.5 Who normally accompanies you when you visit your GP surgery? (Tick all that apply)

No one	Spouse/Partner	Son/Daughter	Parent	Friend/Neighbour	Other
<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆

7.6 When you visit your GP does anyone else usually have to take time off work to accompany you?

If other please specify.....

7.7 When you visit your GP do you usually have to take time off work?

No ₀ Yes ₁

SECTION 8: HEALTHCARE COSTS

8.1 Do you normally pay a prescription charge for medication prescribed by your GP?

- No ₀
- Yes, I pay per item ₁
- Yes, I pay using a prescription prepayment certificate for 3 months ₂
- Yes, I pay using a prescription prepayment certificate for 12 months ₃

8.2 Do you currently receive any of the following?

	NO	YES
Disability Living Allowance (DLA)	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁
Personal Independence Payment (PIP)	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁
Attendance Allowance (AA)	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁
Constant Attendance Allowance (CAA)	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁
Personal Health Budget	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁
Personal Budget from the Council for Social Care	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁

8.3 Do you live in a care home or nursing home?

- No ₀ Yes ₁

8.4a Are you the main carer for someone else (e.g. for a child or relative)?

- No ₀ (if no please go to Question 8.4)

- Yes ₁

8.4b If yes, do you usually have to make alternative care arrangements to allow you to attend your appointments at your GP surgery?

- No ₀

- Yes ₁

8.5 When you visit your GP surgery, do you usually travel by

Transport type		Additional information required
Car/van/motorbike/scooter	<input type="checkbox"/> ₁	a) How many miles is the return journey? miles b) For each visit approximately how much do you spend on parking? £ : p [enter zero if nothing]
Taxi/train/bus	<input type="checkbox"/> ₂	c) Approximately how much is the return fare? £ : p [enter zero if nothing]
On foot/by bicycle	<input type="checkbox"/> ₃	No further information required
Transport provided by the surgery	<input type="checkbox"/> ₄	No further information required
I am housebound and never visit the surgery	<input type="checkbox"/> ₅	No further information required
I am in a carehome and the GP comes to me	<input type="checkbox"/> ₆	No further information required

8.6 Which of these activities do you rely on other people to help you with?
Please tick all that apply and indicate whether you pay for the service, whether it is provided by social services or whether friends, neighbours or relatives provide unpaid help.

	Not applicable or no help	Help paid for by you	Help provided by social services	Unpaid help e.g. family & friends
Cooking	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
Cleaning	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
Shopping	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
Jobs around the house e.g. changing light bulbs, putting the bins out	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
Gardening	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
Childcare	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
Pet care e.g. dog walking	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
Personal care e.g. washing yourself or getting dressed	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
Laundry	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
Social activities outside the home e.g. visiting friends/relatives	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
Attending appointments e.g. at the doctor, dentist, optician	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
Paperwork e.g. paying bills, banking	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
Other (please specify)	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃

SECTION 9: GENERAL INFORMATION ABOUT YOU

Finally, we would like to ask a few general questions. The following questions will help us to see how experiences vary between different groups of people.

9.1 Which of the following statements best describes your situation

- I am filling out this questionnaire by myself ₁
- Someone is helping me to fill out this questionnaire (reading out the questions and marking my answers) ₂
- I am filling out this questionnaire on behalf of someone else ₃

Please make sure that the answers refer to the person who has been invited to take part in the study

9.2 Are you male or female? Male ₁ Female ₂

9.3 How old are you? years of age

9.4 At what age did you leave full-time education?

Please write your age in the box

9.5 Which one of these best describes your current situation?
(Please tick one box only.)

Full-time paid work, including self-employed (30 hours or more each week)	<input type="checkbox"/> ₁
Part-time paid work, including self-employed (under 30 hours each week)	<input type="checkbox"/> ₂
Full-time education at school, college or university	<input type="checkbox"/> ₃
Unemployed	<input type="checkbox"/> ₄
Unable to work due to long term illness/disability	<input type="checkbox"/> ₅
Unable to work due to carer responsibilities	<input type="checkbox"/> ₆
Fully retired from work	<input type="checkbox"/> ₇
Looking after the home	<input type="checkbox"/> ₈
Doing something else (please describe):	<input type="checkbox"/> ₉

Appendix 2. Resource-use information collected at 9 months.

SECTION 7: SERVICES AND COSTS

7.1 Have you stayed in an NHS hospital overnight in the last 6 months?

Yes , No .

You may be contacted by researchers for further information.

7.2 Have you visited an NHS Accident and Emergency (Casualty) department in the last 6 months?

Yes , No .

You may be contacted by researchers for further information.

7.3 How many times have you attended an NHS outpatient clinic or daycase appointment at hospital in the last 6 months?

Please write the total number in the box (*write zero if none*):

For each visit, please give details of the clinic attended and the reason:

Visit 1	Clinic attended:	Reason:
Visit 2	Clinic attended:	Reason:
Visit 3	Clinic attended:	Reason:
Visit 4	Clinic attended:	Reason:

7.4 During the last 6 months, have you had to take time off work to go to hospital appointments?

No .

Yes ,  Number of days off work

7.5 Has anyone else had to take time off work to go to the hospital with you?

No .

Yes ,  Number of days off work

7.6 How many times have you been taken to hospital in an ambulance in the last 6 months?

Please write the total number of journeys in the box (*write zero if none*):

7.7 Please say how many times you have used each of the following NHS services in the last 6 months (*write zero if none*).

	Number of visits/appointments
Occupational therapy	
Speech and language therapy	
Physiotherapy	
Chiropody/podiatry	
Exercise or physical activity scheme or "Exercise on prescription"	
Other (please state)	

7.8 Please say how often you have used each of the following social services in the last 6 months and indicate if this is daily, weekly or monthly (*write zero if none*).

A carer visiting you at home times a day/week/month
Visiting a daycare centre times a day/week/month
Meals on wheels times a day/week/month
Social worker times a day/week/month
Other (please state)	

7.9 Over the last 6 months approximately how much have you spent on non-prescription medicine or therapies? This includes, for example, pain relief, flu remedies, dietary supplements, that you might have bought over-the-counter at the chemist or supermarket? (*write zero if you have not bought anything*)

£-----

7.10 Have you used any private healthcare or therapies in the last 6 months?

No

Yes

→ If yes approximately how much have you spent on these types of private healthcare in the last 6 months?

	Number of visits	Approximate cost
Physiotherapy		£
Acupuncture		£
Counselling		£
Chiropractic		£
Other (please state)		£
		£

Thank you for taking time to complete this questionnaire.

If you have any comments please write them here.

Appendix 3. Resource-use information collected at 15 months.

SECTION 8: SERVICES AND COSTS

8.1 Have you stayed in an NHS hospital overnight in the last 6 months?

Yes , No .

You may be contacted by researchers for further information.

8.2 Have you visited an NHS Accident and Emergency (Casualty) department in the last 6 months?

Yes , No .

You may be contacted by researchers for further information.

8.3 How many times have you attended an NHS outpatient clinic or daycase appointment at hospital in the last 6 months?

Please write the total number in the box (*write zero if none*):

For each visit, please give details of the clinic attended and the reason:

Visit 1	Clinic attended:	Reason:
Visit 2	Clinic attended:	Reason:
Visit 3	Clinic attended:	Reason:
Visit 4	Clinic attended:	Reason:

8.4 During the last 6 months, have you had to take time off work to go to hospital appointments?

No .

Yes .



Number of days off work

8.5 Has anyone else had to take time off work to go to the hospital with you?

No .

Yes .



Number of days off work

8.6 How many times have you been taken to hospital in an ambulance in the last 6 months?

Please write the total number of journeys in the box (*write zero if none*):

8.7 Please say how many times you have used each of the following NHS services in the last 6 months (*write zero if none*).

	Number of visits/appointments
Occupational therapy	
Speech and language therapy	
Physiotherapy	
Chiropody/podiatry	
Exercise or physical activity scheme or "Exercise on prescription"	
Other (please state)	

8.8 Please say how often you have used each of the following social services in the last 6 months and indicate if this is daily, weekly or monthly (*write zero if none*).

A carer visiting you at home times a day/week/month
Visiting a daycare centre times a day/week/month
Meals on wheels times a day/week/month
Social worker times a day/week/month
Other (please state)	

8.9 Over the last 6 months approximately how much have you spent on non-prescription medicine or therapies? This includes, for example, pain relief, flu remedies, dietary supplements, that you might have bought over-the-counter at the chemist or supermarket? (*Write zero if you have not bought anything.*)

£-----

8.10 Have you used any private healthcare or therapies in the last 6 months?

No

Yes

If yes approximately how much have you spent on these types of private healthcare in the last 6 months?

	Number of visits	Approximate cost
Physiotherapy		£
Acupuncture		£
Counselling		£
Chiropractic		£
Other (please state)		£
		£

8.11 This last question is about how things have changed over the last 12 months, since you started the study. For each of the activities listed below, has the amount of help that you rely on from other people increased, decreased or remained the same over the past 12 months?

	Increased	Remained the same	Decreased	Not applicable
Cooking	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
Cleaning	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
Shopping	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
Jobs around the house e.g. changing light bulbs, putting the bins out	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
Gardening	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
Childcare	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
Pet care e.g. dog walking	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
Personal care e.g. washing yourself or getting dressed	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
Laundry	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
Social activities outside the home e.g. attending a day centre	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
Attending appointments e.g. at the doctor, dentist, optician	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
Paperwork e.g. paying bills, banking	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
Other (please specify)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄