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BISCUITS
Bristol Service Costs Study

BISCUIT FINAL REPORT

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Executive summary

Increasingly, NHS commissioners need information about the costs of services to help inform their decision making. Currently, commissioners rely almost entirely on crude cost data to evaluate the economic impact of services, if any cost data are available at all.

The aim of the BISCUIT study was to pilot approaches to economic evaluation of homeopathic packages of care delivered at Bristol Homeopathic Hospital. We wanted to test the methods and outcome tools to facilitate the development of a larger study that could investigate the differences in resource use between those who use NHS homeopathic packages of care and those who do not. Our research question for this feasibility study was:

> *What are the best methods and best outcome tools for undertaking a large scale economic evaluation of a cohort of homeopathic patients compared with a matched control group not using NHS homeopathy?*

To answer this, we used a cost utility model and carried out the first steps of a discrete choice experiment.

Using a prospective matched controlled cohort design, we recruited 29 Bristol Homeopathic Hospital patients from 315 possible candidates, but only received the relevant permissions to access medical records and subsequently found matched controls for nine. Nineteen matched controls returned data.

Qualitative interview data was collected to learn about resource use, experiences of the study and views on the outcome tools for 23 participants. Quantitative data was collected through GP medical record extraction of data such as GP and practice nurse consultations, medications, hospital consultations, tests and investigations. In addition, participant questionnaires were administered to capture wellbeing (Warwick Edinburgh Wellbeing tool), quality of life (SF-36) and resource use (Client Service Resource Inventory). This latter tool collected data on personal costs such as private healthcare, over the counter products, travel and lost earnings. Qualitative data were analysed using qualitative content analysis and a framework approach. Descriptive analyses were carried out on the quantitative data by an independent statistician.

Key findings around feasibility were:

1. There were two major challenges in this feasibility study. The first was the low level of recruitment of case and control participants. The approach adopted whereby case participants were recruited directly from the Bristol Homeopathic Hospital without prior recruitment of their GP practice meant that the pool of potential candidates was substantially reduced when GP practice permission was

not forthcoming. The second challenge was achieving ‘good enough’ matching of cases and controls, which also affected the recruitment of controls.

2. Because only 9 of the original 315 potential candidates from the Bristol Homeopathic Hospital were matched with controls, representativeness is questionable.
3. The outcome tools were feasible, acceptable, sensitive to change and appropriate.
4. Cases and controls were well matched at baseline for quality of life and wellbeing, but not for resource usage.
5. Quality of life for case participants improved compared to controls. Wellbeing for case participants also changed significantly for cases compared with controls. However because this was not a randomised controlled study, we do not know if the improvements seen were due to the Bristol Homeopathic Hospital service.
6. At baseline, costs were substantially higher for case participants. There was no difference in resource utilisation in the 12 months after baseline between cases and controls.
7. If these study results were to apply to other homeopathic case and matched control populations, then 90 participants (1:1 matched) would be needed in a larger study to demonstrate that the quality of life and wellbeing improvements generated by homeopathic packages of care were worth their cost. But because case and control participants were not well matched at baseline for resource use, we do not have complete confidence in this figure.
8. Individual variability in resource utilisation for both cases and controls was substantial.

Given these findings, results should be taken with caution.

In answering our research question, we found that the prospective controlled cohort design produced difficulties in recruitment and matching case and control participants. But the outcomes tools of the SF-36, Warwick Edinburgh Wellbeing and Client Service Resource inventory were acceptable and useful.

The other aspect of this study was to identify key attributes of homeopathic packages of care for a discrete choice model. From interviews with the Bristol Homeopathic Hospital participants, we found the most valued aspects of the treatment were:

- positive impact on health
- the questions that the homeopaths asked
- personalised approach

The most valued aspects of the service were:

- extended length of the consultation
- convenient location of the clinic
- not having to pay for the service

In thinking about designing a larger study, we considered the use of a traditional randomised controlled trial design, which would address known and unknown confounders arising in through matching and lead to the possibility of uncovering a causal connection between the Bristol Homeopathic Hospital service and any changes brought over time. But this type of methodology is difficult to use in evaluating a long-standing service (rather than a treatment) as it does not allow for ‘real life’ decision-making on behalf of patients. There are also ethical issues about denying patients access to an existing, publically funded service, once patients have requested referral.

An alternative could be the use of a Zelens design. In this type of design, the top 20 practices referring into the Bristol Homeopathic Hospital would be recruited first, thereby avoiding the experience in this study of the loss of 40% of participants from GP practice refusal. Then, we would recruit a cohort of patients experiencing the top five conditions treated by the Bristol Homeopathic Hospital from these 20 practices. As patients are referred into the Bristol Homeopathic Hospital and recruited, they would be matched with community controls from any of the 20 practices on the basis of condition, symptom, age within 5 years and a resource use proxy measure of GP consultations (within 2 consultations) in the past year.

The advantages of this approach is that it reflects ‘real life’ by not tampering with patient decision-making and would hopefully lead to much closer matching at baseline between case and control participants. The disadvantages are that without randomisation, known and unknown confounders could affect any observed changes over time and there is no blinding. Moreover, we know that individual doctors do vary substantially in their referral patterns, which would impact on patient resource use, and this needs to be taken into account in this design. Nonetheless, this Zelens approach would be a step closer to developing a robust study of economic evaluation of the Bristol Homeopathic Hospital.

Although undeniably challenging, the importance of designing good quality economic evaluations for generalist services like the Bristol Homeopathic Hospital is important. Therefore, we would encourage future researchers to work through the methodological difficulties of conducting economic evaluations of services to ensure NHS commissioners - and the wider public - have the information necessary to make appropriate judgments.

Acknowledgements

We thank our funders, Blackie Foundation, the British Homeopathic Association, South West GP Trust and United Hospitals Bristol Above and Beyond Fund.

We thank all of the case and control participants who have taken the time to respond to questionnaires. We also would like to thank the GP practice staff who gave permission to access patient records and those who carried out the searches. In addition, Susan Barron, departmental manager at the Bristol Homeopathic Hospital, and the Homeopathic Hospital staff were instrumental in recruiting case participants.

Vicky Burrows, a fifth year medical student, dedicated a period of self-study to help set this project up. Patricia Martens continued with the administrative tasks. Hallam Wye checked data entry. Tom Griffin was the independent statistician. Lorna Duncan conducted the majority of participant interviews and acted as research assistant.

Thanks also go to our steering group and wider advisors. The steering group consisted of Dr Elizabeth Thompson, lead clinician at the Homeopathic Hospital, Professor William Hamilton (Peninsula Medical School) and Professor Debbie Sharp (University of Bristol). Many economists contributed their time and expertise including Dr Richard Fordham (University of East Anglia), A-la Park and Dr David McDaid (London School of Economics), Professor Will Hollingworth and Sandra Hollinghurst (University of Bristol). Dr Helen Baxter gave advice about recruiting cases, controls and GP practices early on in the study. Tim Wye, formerly Associate Director of Commissioning at North Somerset Primary Care Trust, provided useful insight into commissioners.

Finally, a special mention to Professor Gene Feder, who is not a member of the study team or an advisor, but who spoke at an ethics committee meeting on our behalf when ethical approval was threatened.

We are grateful to all for their support of this study.

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Overview

Introduction

Background to the study

Increasingly, NHS commissioners need information about the costs of services to help inform their decision making. Currently, commissioners rely almost entirely on crude cost data to evaluate the economic impact of services, if any cost data are available at all. The aim of the BISCUIT study is to pilot alternative ways of economically evaluating homeopathic packages of care delivered at the Bristol Homeopathic Hospital.

The Homeopathic Hospital is a good site for testing economic evaluation approaches for several reasons. First, as the Homeopathic Hospital takes referrals from across the South West for patients with any condition, this provides access to a broad range of commissioning areas, GP practices and patients. Second, there is a great deal of controversy around the continued funding of the Homeopathic Hospital; and so information about its impact on costs would be very welcome. Third, the lead clinician for the Homeopathic Hospital was enthusiastic about the study and helped facilitate access.

We obtained funding from four sources. Two homeopathic research charities: the Blackie Foundation and the British Homeopathic Association contributed £22,900 and £10,000 each. The South West GP Trust allocated £10,536 and the Above and Beyond Fund of United Hospitals Bristol contributed £12,035. We are grateful to all of our funders.

Study design

The aim of the BISCUIT study was to pilot approaches to economic evaluation homeopathic packages of care delivered at Bristol Homeopathic Hospital. This was a mixed methods study. Our research question for this feasibility study was:

> *What are the best methods and best outcome tools for undertaking a large scale economic evaluation of a cohort of homeopathic patients compared with a matched control group not using NHS homeopathy?*

The intention was to test the methods and outcome tools to facilitate the development of a larger study. The research question for this larger study was: What difference in resource use is there between those who use homeopathic packages of care within a NHS setting and those who use only conventional care? In collecting data for the feasibility study, we partially answered this larger question through qualitative interviews and preliminary quantitative analyses. However, because our sample was very small and there were substantial limitations to this study, these preliminary findings must be viewed with caution.

In addition to these over-arching research questions, we developed several sub-questions including:

- Is data extraction feasible?
- How will we power the larger study?
- Are the outcome measures acceptable, feasible and appropriate?
- What characteristics do patients believe are important in their healthcare which can be developed into attributes to use in a discrete choice model?
- Why might patients currently receiving homeopathic packages of care continue or stop using other NHS resources?
- Can we find comparable controls to homeopathic case patients?

To answer these questions, we developed a mixed methods study with a prospective controlled cohort design.

Our plan was to recruit 20 newly referred patients to the Homeopathic Hospital and match them with five controls from the same practice on sex, age within five years and condition. To track the NHS and personal resource usage of the cases and controls over the period of a year, we sent out a questionnaire every three months by post. This questionnaire measured wellbeing (Warwick Edinburgh Wellbeing), quality of life (SF-36) and resource usage (Client Service Resource Inventory). In total, there were five time points when questionnaires were administered. Two to four months after the final questionnaire was due, we interviewed cases and controls to explore their experiences of the study (e.g. questionnaire, recruitment processes), their usage of NHS and personal resources and their treatments (e.g. combining use of homeopathy and biomedicine - cases only). We also re-visited GP surgeries to extract GP medical record data on NHS service usage. Details on how both quantitative and qualitative data were analysed are included later in this report.

Findings from interim report

In October 2010, we published an interim report that focused on ethics and recruitment (Wye 2010). The key findings from this report were:

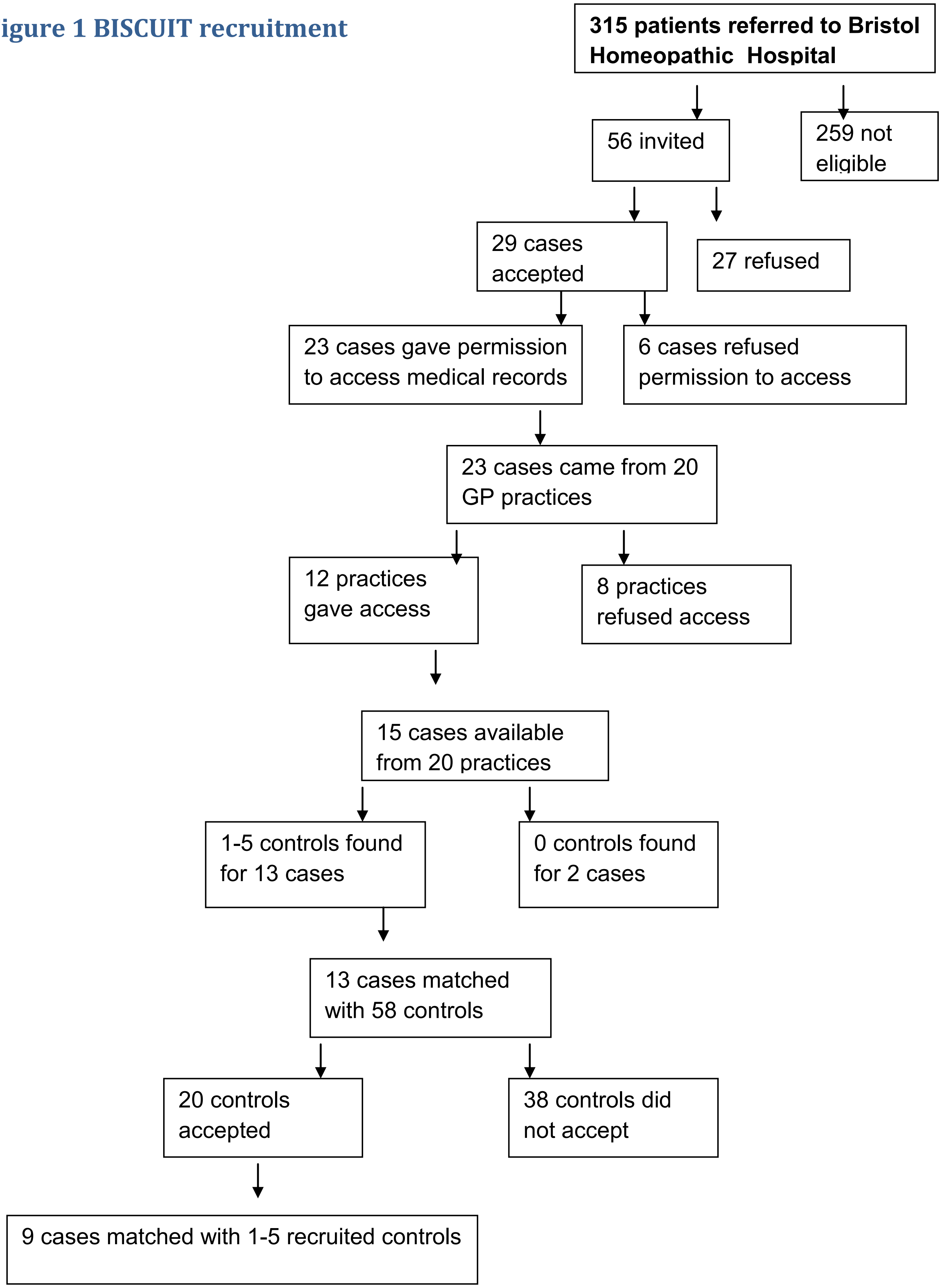
- Obtaining research governance approvals was a lengthy process, as the ethics committees and all seven R&D offices missed their 60 day deadlines by 10-42 days. It is not unrealistic to allocate at least 8 months to research governance.
- Recruitment for case participants began in January 2010. We originally estimated that it would take 3 weeks to recruit 20 cases from the Bristol Homeopathic Hospital. In fact, it took nearly 6 months, as 82% of referrals (259/315) did not

meet our criteria. Nearly 40% of those who did not meet the criteria (119/259) were excluded as there was less than 4 weeks between the study team learning of the appointment date and the actual appointment date. This criterion was in place to ensure that potential cases had completed the baseline questionnaire before their first consultation at the Homeopathic Hospital. This problem occurred because with the drop in referrals patients are no longer waiting as long for an appointment as they used to and this was not predicted.

- 56 invitations were sent out to those meeting our criteria for case participants; 29 accepted and filled in baseline questionnaires (52%). Of those 29, 6 refused permission for researchers to look at their medical records, which left 23 case participants from 20 GP practices eligible for control matching.
- Of 20 GP practices, 8 refused access to researchers for a variety of reasons, primarily due to pressures within the practice or a lack of interest. This left 15 cases.
- Of the 15 cases, 10 were matched with 5 potential controls. For two cases, no controls were found. For the remaining 3 cases, we found between one and four controls. The 13 cases were matched with 58 controls.
- Of the 58 controls invited, 20 accepted the invitation, giving a response rate of 34%. In total, we recruited 1-5 controls for 9 of the 15 cases.
- We were able to match 9 of the original 56 case participants to 1-5 controls.

Figure 1 below gives an overview of recruitment.

Figure 1 BISCUIT recruitment



The five key stages at which potential participants were lost included:

1. Referral to the Bristol Homeopathic Hospital to study invitation (259/315 referrals not eligible, 82%)
2. Study invitation accepted by potential case participant (27/56 refused, 49%)
3. GP practice permitted searching for controls (8/20 practices refused, 45%)
4. Identification of 5 potential controls for every case (5/15 cases 5 controls not identified, 33%)
5. Study invitation accepted by potential control participants (38/58 refused, 66%)

Given these findings, to improve recruitment we recommended:

- Face to face recruitment of case participants through the homeopathic physician, Homeopathic Hospital administrative staff or a researcher on the premises at the time of the first appointment might be more effective. This needed to be tested out in interviews with participants in the second phase of the study.
- Consider recruiting only homeopathic patients with common conditions such as depression, hot flushes and fatigue.
- Recruit GP practices *before* recruitment of Homeopathic Hospital patients.
- Limit recruitment of GP practices to those practices with a list size of 7,500 or more so control participants were more likely to be found.

Aims of this report

To answer our over-arching research question on the best methods and best outcome tools for carrying out an economic evaluation of homeopathic packages of care, the aims of this final report are to:

1. Discuss the feasibility of data extraction from GP medical records.
2. Present preliminary quantitative findings on:
    a. The differences between case and control participants in term of resource use, quality of life and wellbeing.
    b. Power calculations for a larger study.
3. Present findings on:

    a. The acceptability, feasibility and appropriateness of the study methods and outcome tools from the viewpoint of the participants.
    b. The attributes of value to homeopathic case participants which could be developed into a discrete choice model.
    c. Ways in which participants accessed and consumed healthcare resources
4. Explore the degree of comparability between case and control participants.

Because this report focuses heavily on the processes of gathering data, it has not been designed with the traditional structure of Introduction-Methods-Results-Discussion. Instead, the first section concentrates on data collection processes, the second on the quantitative component of the study and the third on findings on the feasibility of the study methods and tools, as well as attributes for a discrete choice model. The fourth section discusses issues around matching cases and controls and ways in which healthcare resources are used. The report finishes with a discussion section with responses to our research questions.

The next section on data collection begins with a discussion of General Practice medical record extraction.

Part I Data collection

General Practice medical record extraction

BISCUIT GP surgery re-visits

Required data

We had permission to extract medical records for 15 case participants (9 of whom were matched with controls) and 19 controls from 12 different GP surgeries. The data we wanted to collect for each participant were:

- GP and practice nurse consultation notes
- Letters of hospital out-patient consultations, A&E visits and hospital admissions
- NHS community service usage
- Hospital tests e.g. x-rays, MRIs etc.
- Laboratory tests e.g. blood, urine
- Sick notes
- Prescription medications

We wanted baseline data for cases and their associated controls for 12 months before the index date of the first homeopathic consultation for the case participant. Intervention year data were needed for 12 months after the index date of the first homeopathic case consultation. For example, if the first homeopathic consultation took place for a case on 1 March 2010, then the baseline dates for the case participant and his/ her controls were 1 March 2009 – 28 February 2010 and the dates for the intervention year were 1 March 2010 – 28 February 2011.

Medical record data were needed for two reasons: 1) to calculate resource usage and 2) to inform the qualitative interviews with participants. The qualitative interviews were scheduled to take place 2-4 months after the one year anniversary of the date of the first homeopathic consultation for the case participants. This timeframe was chosen as it was anticipated that the study would still be relatively fresh in their minds. This also allowed sufficient time for the medical record data to be extracted from the GP practice and analysed.

Scheduling re-visit dates

The project lead (LW) or the project administrator (PM) began contacting the surgeries about two weeks before the anniversary date of the first appointment.

Using e-mail, we contacted the surgery staff member who had furnished the data approximately a year earlier when we first visited the practices to identify controls to arrange a date for a revisit. This was relatively straight forward for all but four of the practices. In three practices this was because the contact person said they were too busy for a re-visit or were taking annual leave. In the fourth, the original contact person had left the practice and a new contact person needed to be located. For these four practices, it took the administrator several e-mails and telephone calls before a date was arranged.

Three of the twelve practices which we planned to revisit had two cases, as well as diverse numbers of controls. This meant working with two different anniversary dates of the first homeopathic consultation in timing the GP practice re-visits. For one practice, this was not problematic as the anniversary dates were within four days of each other, and so we re-visited after the last anniversary date. For another practice, the anniversary dates were 10 weeks apart. As the first anniversary date was for a case participant without controls, and therefore was less likely to be sampled in the qualitative interviews, we re-visited after the anniversary date for the second case. For the third practice, where both cases were matched with controls and the anniversary dates were over three months apart, we re-visited the practice twice, once after the first case anniversary date in March 2010 and then again after the second case anniversary date in June 2010.

Six of the twelve practices were re-visited within two weeks of the case anniversary date; three were re-visited within five weeks of the case anniversary date; two were re-visited about seven weeks after the case anniversary date and one sent data by post and was not re-visited. Several practices were visited later than planned because there was a bottleneck in mid-April as anniversary dates for six cases from six different practices came up. This period coincided with the Easter holidays for 2011, which were then followed by the Royal Wedding and the early May bank holiday. Many NHS staff took annual leave during this period, which made it difficult to find dates.

One practice was not re-visited as only one set of records was needed, the practice was located about 2 hours away from the University and the staff contact manager was a highly capable IT manager who said he could download and print the data himself. However, the research administrator and the project lead had to e-mail and ring several times before the data were produced. The IT manager then suggested sending the data electronically via NHS net. To obtain this electronic file, we needed someone with a NHS Net account who was happy to receive these data. LW contacted several academic GPs within her department, none of whom used or had access to their NHS Net account. She then contacted a community nurse who did have a NHS Net account. However, when the nurse received the electronic data, and realised that the records had not been anonymised, she deleted the file as she believed she was contravening patient confidentiality rules. Eventually, LW found a GP within her department who was happy to receive the file without looking at it. The GP alerted the study administrator who transferred the electronic data to the study file on the secure University server.

Process of extracting and recording medical record data

A visit to one practice early on resulted in the development of a protocol to extract the required data in EMIS that could be used by other practices. They put these instructions into a document that LW then used with all other practices (see Appendix A).

Two practices were happy to let LW extract data by herself. One provided a separate room and no staff member was present; the other offered to a staff member to help as LW was unfamiliar with the IT system. The majority of practices either insisted or preferred that a staff member download the data, often using the EMIS instruction guide. In these cases, as the staff member produced the documents and LW would anonymise them.

We considered several ways of recording medical data. One option was to directly input data from the medical records into an Access database held on a laptop. This alternative was discarded because previous experience with medical record data suggested that it would be difficult to pre-program all the necessary data fields. Another option was to take handwritten notes while in the surgery. This method was attempted at the first GP surgery visit, but was found to be excessively time consuming (ie it took LW more than one hour to access and copy all the data for one participant). A further concern was that time was needed to corroborate the details in the notes (e.g. hospital referrals with letters from hospital doctors confirming the referral was taken up), preferably outside the GP practice surgery so cross referencing could be done at leisure. So the most efficient method was to request printed copies of all of the relevant medical record data for each participant for the baseline and intervention years, anonymise these data and bring the documents back to the University for analysis.

Consent and anonymity

When visiting each practice, we created a case file with copies of the patient consent form to access their records, an information sheet on the study and local R&D ethical approval. Although we had already furnished these documents, several practices requested this information again before agreeing to extract the required data.

Once the data had been generated, it needed to be anonymised. This was unproblematic for the GP surgery consultation, test and medication notes as the headers containing patient identifiable details could be deleted before printing. For hospital related documents LW cut out chunks of patient identifiable data using scissors and where these data were embedded, a black pen was used to cross the name out. The patient identifiable details that were exorcised included name, contact details and NHS number. All front cover documents were then given the study number of the participant.

Time

It took roughly 20 minutes per record to extract and anonymise documents. However, for three practices data collection per record took much longer because of technical problems, either with the IT system or because of printing difficulties (or both) or because of the inexperience of the staff member with EMIS. For one practice, which had two premises, a new computer system had been installed and the staff member could only get hospital data from the computer at the other premises. To get these data, LW went to each practice, without luck. Eventually, the anonymised hospital consultation data was sent via post. However, the data received did not appear to be complete, with several corroborating hospital doctors' letters missing.

Costs

Although six of the practices charged the study for the first set of visits to identify controls and send out invitations (see October 2010 interim report), only four of those subsequently charged for medical record extraction. Charges varied from £20-£50 with a cost per hour of £25-£40 and three of the four practices charged according to time spent. One practice charged £35 as a standard administration fee for patient records.

The table below gives details of the practice re-visits.

Table 1 Details of practice revisits

Practice	No. record	Anniversary date of appointment	Date(s) practice visited	Staff member contact	Who extracted data	By hand or post?	Time	Cost	Cost per hour	Issues
Bristol urban 2	3	1.3.2011 10.6.2011	9.3.11 22.3.11 21.6.11	IT manager	LW	By hand	2 hrs 1 hr 1 hr	0	0	Piloting method & 2 cases so multiple visits
Somerset market 1	5	15.3.2011	23.3.11	Research admin	Research admin	By hand	2 hrs	£50	£25	
Somerset market 3	1	24.3.2011	29.3.11	Research nurse	Research nurse	By hand	20 mins	0	0	
Gloucestershire urban	3	25.3.2011	5.4.11	Admin staff	Admin staff	By hand	1 hr	0	0	
Gloucetershire rural	1	19.4.2011	10.6.11	Practice manager	Practice manager	By hand	30 mins	£20	£40	Difficulties re-gaining access
South Glos rural	3	20.4.11	26.5.11	GP	GP	By hand	20 mins	0	0	Difficulties in pinning GP down

Practice	No. re-cord	Anniversary date of appointment	Date(s) practice visited	Staff member contact	Who extracted data	Visit or post?	Time	Cost	Cost per hour	Issues
Bristol urban 3	1	20.4.11	15.6.11 20.6.11 22.6.11	Practice manager	Admin	By hand Post	30 mins	0	0	Technical problems so visited practice 3x, eventually received by post
Bristol urban 4	1	21.4.11	24.5.11	Practice manager	Practice manager	By hand	0 mins	£35	NK	Data already printed by staff. LW collected envelope & anonymised on site
Bristol urban 1	6	22.4.11	11.5.11	IT manager	IT manager	By hand	90 mins	0	0	Problems with printer

Practice	No. re-cord	Anniversary date of appointment	Date(s) practice visited	Staff member contact	Who extracted data	Method of obtaining data	Time	Cost	Cost per hour	Issues
Somerset rural	2	23.4.11	4.5.11	Practice manager	Practice manager	By hand	2 hrs	£25	£12.50	Technical problems eg EMIS glitch, printer broke down
Devon rural	1	20.5.11	No visit	IT manager	IT manager	Post	NK	0	0	Data sent electronically, several problems of confidentiality
Somerset market 2	4	24.5.11	28.6.11	Admin	LW with admin help	By hand	1 hr	0	0	Original contact left practice resulting in delay to find new contact

Key learning points

- The process of scheduling re-visits should start about two weeks before the anniversary of the first case appointment.
- Holidays and the coinciding of several anniversary dates during the same time period can substantially affect the re-scheduling of visits.
- Further delay in re-scheduling visits can come about if the original staff member has left the practice and the process of relationship building needs to start anew.
- Case site files with the relevant patient consent forms, study information sheets and R&D approvals should accompany the researcher on each visit. A researcher also needs to bring along a heavy black pen, a set of scissors and folders for the records.
- The best way to collect the data is to download all of the relevant information while on GP surgery premises, print it and take it away, once it is anonymised. This then gives the researchers the opportunity to extract, cross reference and input the relevant data at leisure.
- Practices are unlikely to let a researcher have direct, unsupervised access to their IT systems.
- Sending data electronically is difficult, because of the problems in accessing NHS Net, and may challenge data protection guidelines.
- Although visiting practices is time consuming, personal visits do ensure that all the data required are downloaded and that the GP staff member makes time to carry out this task.
- If everything is running smoothly, it takes about 20 minutes to download, print and anonymise one set of medical records.
- Only a third of the practices took up the offer to be financially reimbursed for their time, most basing their charges on time spent. However, if practices charge per record, the costs are higher per record.

The next section reports on questionnaire completion and data extraction from the GP medical records.

Questionnaires and medical records

Questionnaire administration and entry

All case and control participants were asked to complete a document that combined the Warwick Edinburgh Wellbeing tool, SF-36 and the adapted Client Service Resource Inventory at five time points. This was sent by post every three months. To encourage return, we included post-it notes with hand written messages and incentives. For example, at an early time point, we added a tea bag with a note saying 'have a cup of tea on us!'. This did not appear to increase either the rate or speed of returns.

Initially, if a questionnaire was not returned, we sent out another copy. But this caused confusion. So instead the project administrator rang, e-mailed or texted participants to chase up outstanding returns. As a result, about 80% of the study population returned all 5 of their questionnaires. We found maximizing the personal contact between the study team and the participants helped with retention.

All administrative details around the questionnaires (e.g. date sent out, date returned etc.) were logged in an Access database. Returned questionnaires were acknowledged with a handwritten thank you note and a £5 high street voucher.

We found that questionnaires were usually complete, with only the occasional questionnaire with one or two questions missing. Data from the questionnaires was entered by the project administrator into an Access database at the end of the study. All data entries were then double checked by an independent administrator to ensure accuracy. On reflection, entering the questionnaires as the study progressed would have been useful as participants sometimes wrote personal notes that needed attention.

Contents of GP practice medical records

The aim of collecting medical record data was: 1) to compare types of data available from medical records and participant questionnaires, 2) to determine the accuracy of the two sources and 3) to create a 'master' record combining medical record and participant questionnaire data that could be analysed for NHS and personal costs.

For the purposes of this study, GP practice medical record information that we extracted can be sub-grouped into three main sections: 1) primary care consultation, 2) medication and 3) attached letters, usually from hospital and community services.

The primary care consultation record was a running chronicle. It included dated, chronological information on every patient contact, referral, secondary and community care contact, tests requested and test results. Within that consultation record, GP contact data tended to give details on symptoms, condition, medications prescribed, intended referrals and tests requested. Practice nurse contact data was much terser and tend to list tests and in rarer cases, advice given. The primary care consultation data provided an overall narrative which was then corroborated in the other sections of the medical record, namely medication and hospital and community service contacts.

The medication data appeared in a separate listing. Prescribed medications were listed in chronological order and included details on date prescribed, name of medication, strength, prescribed dose, type of preparation (e.g. capsules, ointment), amount available per prescription (e.g. 28 tablets per box) and sometimes the British National Formulary (BNF) code. Some systems separated out repeat prescriptions from one-off and past prescriptions.

The attached documents came from a variety of sources. These documents were much less standardised than the primary care consultation or medication data and included:

- referrals, including service specific referral forms, generic forms to choose and book and letters from GPs to hospital doctors
- letters to GPs from hospital practitioners, mainly doctors, with information on patient visits
- letters from patients to their doctors providing updates or asking for letters to be written on their behalf e.g. to housing associations or benefits agencies
- test results e.g. ECG traces
- laboratory results e.g. cervical smear reports
- letters from outside agencies asking for medical record details e.g. health insurers, benefits agencies

Sources and quality of medical record information

For costing service usage, the data we wanted for each participant were:

- GP and practice nurse consultations
- Hospital out-patient consultations, A&E and hospital admissions
- NHS community service usage
- Hospital tests e.g. x-rays, MRIs etc.
- Laboratory tests e.g. blood, urine
- Sick notes
- Prescription medications including bandages and NHS equipment

Within the primary care consultation section, GP consultations were recorded as face to face or telephone, which was important information as they attracted different prices. The price for practice nurse consultation was standard. In all but one GP IT system, it was clear whether a doctor or a practice nurse consultation had taken place because the details included the name of the practitioner with their title (Dr for GP and either Sister or Miss/ Ms/ Mrs or Mr for a nurse). For the one practice where only initials were provided, LW asked for this information.

For out-patient hospital consultations, referral letters were not sufficient to confirm out-patient attendance, as some participants did not take up the offer of a referral. However, referral letters did often provide useful new or corroborating information on medications or previous investigations. Confirmation of hospital out-patient attendance came from letters from secondary care providers, which appeared to be sent after every patient contact.

These included details on the date of the clinic, status of the doctor, hospital tests conducted and future follow up. Letters from other hospital care providers e.g. psychologists in oncology or the ME clinic and community clinic providers e.g. musculo-skeletal clinics only appeared to be sent at the start or end of a series of visits. Letters from these practitioners often did not include details on practitioner consulted, dates or investigations. So, medical record data was not robust enough to cost non-doctor out-patient hospital visits accurately.

None of our participants visited acute hospital A&E departments during the study period. Documentation from minor injuries units and in-patient hospital admissions tended to be faxes or discharge letters from the hospital. These would include details on date, condition, hospital treatment, hospital prescribed medication and suggestions for follow up. These appeared to be robust data, although there was no corroborating evidence with the medical record.

Referrals to community services tended to be standardised forms. Sometimes it was difficult to know whether a service, particularly physiotherapy, was hospital or community based. Discharge letters would often include details on total number of visits, but not when these visits had occurred.

Information on hospital tests that the GP had requested such as ECGs could be found in the GP consultation record, often along with a copy of the test results. Information on hospital tests ordered by hospital doctors was harder to find. For example, letters from hospital doctors to GPs would often mention that x-rays or MRIs had been carried out, but no other documentation confirmed this.

Laboratory tests, however, could be corroborated. In the primary care consultation record, GPs would often list all of the different tests that they wanted carried out, often in abbreviated form. So, for example, from a blood test, the GP might write “FBC, LFT, TFT” and so on. This would stand for full blood count, liver function test and thyroid function test. Elsewhere in the primary care consultation record, the practice nurse would record that the requests for these tests and the results were also entered, sometimes with an indication of which doctor had looked at the test results. Further corroboration was available as some IT systems also separated out all of the laboratory tests requested and the ‘values’.

Sick note data were less well recorded. Sometimes a doctor might note “MED3 until (date)” which indicated that a sick note had been issued. But often there were gaps and the total number of days was hard to identify for the long term sick. Occasionally, it was possible to corroborate sick note information from patient letters to their doctors or letters from doctors to outside benefits or insurance agencies.

Prescription medication information was often recorded briefly in the primary care consultation record, as well as in separate prescription lists where full details were provided. Sometimes a medication would appear in the prescription list that was not recorded in the primary care consultation record and vice versa.

Medical record data extraction form

Originally, we had hoped to use the same form to extract medical record data that had been sent to participants. This form was adapted from the Client Service Resource Inventory. (see Appendix B) However, once medical records were obtained, we realised that these provided much more useful data for costing in certain areas, specifically tests, medications and GP consultations.

For tests, the participant questionnaire was highly hospital focused itemising MRI, CAT scans, ultrasounds, x-rays and EEGs. The exception was ‘blood tests’. However, from looking at the primary care consultation record, we learnt that from one blood sample anywhere from one to twenty tests might have been requested. There were over 90 different laboratory tests recorded in participants’ records. To capture more detailed information on test type, we modified the tests section of the medical record data extraction form.

For medications, the patient questionnaire asked for name, new or repeated, reason for use and ‘how often do you take it?’ This was insufficient data to cost the medications, however the medical record data, with added details of strength, amount and sometimes BNF code, did provide sufficient information and so the medical record data extraction form was amended accordingly.

For GP consultations, the participant questionnaire only asked for total number of consultations. The primary care consultation data broke this total down into telephone and face to face consultations, which was necessary for more accurate costing and so again the medical record data extraction form was modified. For a copy of the amended form used for GP medical record data extraction, please see Appendix C.

Assumptions

To standardise data extraction, we made several assumptions namely:

- For blood and urine tests, if a practice nurse recorded sending off a sample, then we assumed a practice nurse consultation took place.
- GP DNA (did not attend) were counted as a consultation that took place, as they used NHS resources.
- If medical records listed a date for a GP consultation, but no other information was given, we assumed this was an administrative error and did not count this.
- If GP consultation was recorded but no information was given on whether it was a telephone or face to face consultation, we assumed face to face.
- If the GP telephoned and there was no answer, we did not count this as a GP consultation.
- If a hospital test or investigation was mentioned in a consultant letter, we recorded that one test or investigation had taken place, even if two x-rays or EEGs could have been possible, for example.

- Unless otherwise informed, we assumed that the date of the hospital test or investigation was the same date as the out-patient clinic.
- If we knew from participant questionnaires that a prescription was repeated but had no information from medical records to state when or how often the prescription was filled, we only input the dates for the prescriptions listed in the medical records. We did not try to guess how many times the prescription had been issued.
- If a referral letter to a consultant listed that a prescription had been issued, which did not appear in the primary care consultation notes or prescription record for that time period then we assumed that the prescription was not taken. If a referral letter mentioned a prescription was taken and the primary care consultation notes mentioned the drug, but it was not listed in the prescription record, we recorded that a prescription had been issued.
- Unless otherwise stated, we assumed that A&E attendances were walk-ins, not via paramedics.
- If we suspected that a participant was taking a repeat medication throughout the study time period but it was not recorded as issued in the medical record, we did not include it.
- If the primary care consultation notes listed that a prescription was issued, but it did not appear in the prescription list, we recorded the prescription as issued.
- We recorded tests from the date in which the sample was taken, except in cases where this information was not given. In which case we recorded as the date of results.

Corroboration

Those assumptions aside, an aim of this exercise was to create an accurate NHS usage record for every participant. Given the variable quality of the data, we trusted certain data from the medical records more than others, either because the data appeared consistently well recorded (e.g. GP consultations) or the documentation was convincing (e.g. ECG traces). The following items that appeared to have robust data:

- GP and practice nurse consultations
- Hospital out-patient consultations delivered by a doctor
- Minor injuries unit
- Hospital in-patient admissions
- Hospital tests with documented results
- Laboratory tests

In extracting these data, we did not look for corroborative evidence.

For other data, we were less sure and sought corroboration of information across sources. For example, with non-doctor hospital consultations and community service consultations, if total number of consultations were not recorded, we checked the participant questionnaire and took on trust the number of visits reported by the participant. If the participant questionnaire did not have these data and there was no further information, we assumed that the service had been used once. Exceptions were when letters stated that the service had been used “fortnightly for the past year”, in which case we estimated 24 visits.

The trustworthiness of prescription data was variable. We primarily drew on data from the GP prescription record. This was cross-referenced against the primary care consultation data to identify any medications possibly prescribed by a GP but not recorded in the prescription record. We also turned to participant questionnaires for further corroboration. With this cross checking, we trusted the accuracy of the data confirmed against all three of these sources. The data for one off medications prescribed by a GP tended to concur across sources. For repeat prescriptions prescribed by a GP, however the data were more dubious. Although we could ascertain across sources that a particular drug was taken regularly, often the medical records did not provide accurate or sufficient information on how often the prescription was filled. Our choice was to either guesstimate number of prescriptions by working out dose and checking against the number of recorded prescriptions or to only count the prescriptions itemized in the prescription and primary care consultation records. We took the latter course.

For hospital prescriptions, we often only had the name of the prescription and unless we could find further particulars in the primary care record data, it was not possible to price these medications and so this information was left out.

Process of extracting medical record data

LW extracted all of the medical record data. For each participant, two medical extraction resource forms were printed: one each for baseline and intervention year. Using the date of the first homeopathic appointment, LW would complete the date fields for baseline and intervention years. The next step was to go through the primary care consultations, medications and attachments to eliminate any information that did not pertain to those two dates and separate all remaining data into baseline and intervention years.

Starting with baseline data, LW would read through the primary care consultation record, highlighting GP and PN consultations and getting a feel for the case. If the record was long, she would also highlight prescription and referral information mentioned in the text. Depending on the case, LW would then either extract GP and PN consultation data first, if there were numerous consultations, or hospital data, as it was on the first page of the medical extraction form.

For GP and practice nurse consultations, LW would go back to the start of the baseline year of the primary care consultation record. She noted the dates of all GP and practice nurse contacts on the medical extraction form and then added them up to get a total number. Simultaneously, LW would record GP laboratory tests with dates and occasionally the name and date of prescription medication, as recorded in the primary care consultation record. If sick notes were mentioned, LW also recorded the number and dates of sick notes.

For hospital usage, LW would read all the documents and fill in the appropriate fields for A&E usage, overnight stays and out-patient consultations such as date, department or specialty and for out-patients type of practitioner visited (e.g. doctor or nurse). If hospital tests or investigations were mentioned, the date was recorded in the tests table. If any prescription medications were mentioned in consultant letters, LW would record the name of the medication in the medication table to check against the primary care consultation record.

Extracting community service involved reading the documentation, noting the type of service used, the dates and number of visits.

The medication table was usually completed last. LW first looked at the prescription medication record and recorded all relevant details such as name, date prescribed, amount etc. She then went back to check this information against the primary care consultation record.

LW then repeated this same process for the intervention year, however the further source of the participant questionnaires were used to corroborate key data such as prescriptions.

Difficulties and discrepancies

The greatest challenges came with extracting medication data. Medical record data were often inconsistent. From LW's notes

> *Every set of patient notes is a bit like unraveling a mystery. For example with participant 14, I looked at GP consultation notes and on 28.8.09 the GP has written that the patient is intolerant to mirtazapine and to try dothipin. But the prescription records have nothing about either drug for that date and the list of drugs for that baseline year does not include anything resembling 'dothipin'. Medical records for the next year does list 'dosulepin', which looks like it's the same thing. To check how long the participant had been having it, I then looked at her baseline questionnaire dated 26.4.10 and she lists 'dulsupin 1 each night'. However, 'dosulepin' is first entered in the medical records with the date of 14.7.10 – nearly three months after the patient mentions she's taking it. So this leads me to believe that:*
>
> 1. *The medical record for prescribed drugs is not complete.*
> 2. *Dothipin, dosulepin and dulsupin could all be the same thing.*
> 3. *Participant 14 has been taking that medication since 28.8.09 (Research log, 28.5.11)*

In some GP systems, the number of repeat prescriptions was easier to calculate but other difficulties were thrown up.

> *Medications in X practice – much clearer system for tracking prescriptions. So they have a medication listed and it says 'acute' or 'repeat' and also gives the date of the last prescription. But it doesn't give the BNF code. Tests in this system good as has a list of all investigations itemized with dates. Downside of these records – consultations written in such a way that it's not clear when the GP is reviewing tests or the patient is consulting. (Research log, 19.8.11)*

Moreover, although improved, there were still problems in even this more advanced system with repeat prescriptions. When LW was extracting medical record data from this GP IT system for a different participant, she found a repeat medication was prescribed on 22.5.10 and 9.6.10 and then the next date listed was 18.3.11, although the participant questionnaires indicated that the medication was taken continually from June 2010 to March 2011. For the purposes of data extraction, LW counted three prescriptions in total: 22.5.10, 9.6.10 and 18.3.11.

Sometimes the errors in medication appeared to run across several sources. So the prescription medication records for one participant listed that he took diclofenac from March 2009, and this was stated in his referral information. However, this medication was only listed once in his prescription record and not as a repeat medication. Moreover, the participant stated in his questionnaires that he did not take any medication at all. In this case, given the confusion, we tended to accept the participant's account.

One GP IT system (65976) held little useful information, perhaps because it was so new and the GP staff did not know how to use it. There was no list of prescription medication, other than that held in the primary care consultation record. Referrals were mentioned but there was no attached documentation to check if the participant followed through. Unusual terms were used for GP consultations such as "indirect encounter". In this case, the participant questionnaires were invaluable.

A further difficulty is that for one participant, we learnt that medical information was kept from her. Her medical records noted that she has a suspicious discharge and so she received a rapid referral. Notes recorded that the "Patient was told X referral to exclude any abnormality. CANCER NOT MENTIONED" (emphasis from notes). This turned out to be a false alarm. However, the researchers were in an ethical dilemma as they had more information about the participant's health than she did herself. This could have made the interview difficult.

Changes to the resource form

Having looked at the medical records and the participant questionnaires, we suggest the following changes to the resource questionnaire and medical record extraction tool for the larger study.

For both forms:

- For every questionnaire include two participant identifiers so lost questionnaires can be found.
- Add boxes for:

    - out of hours
    - Day surgery
    - Ambulance

- ‘Counsellor’ needs to distinguish between NHS and private.
- Need to consider how/ whether to separate NHS and private provider resource use.
- Cut down on rows for A&E visits and overnight stays as not used much.
- Need more rows for out-patient visits with spaces for dates.
- Need date for hospital tests.
- Fewer boxes are needed in the GP and community service list. For example for this participant population, we did not need district nurse, health visitor, pharmacist or social care costs like home helps and care attendants.
- Distinguish between the recording of hospital and community physiotherapists.
- For GP and Community health services, add dates of visits.
- For A&E need to ask which hospital went to to separate out casualty and minor injuries visits.

For participant questionnaire

- Eliminate question on ‘Have you gone to hospital in the last year?’ as often not answered and sometimes participants say ‘no’ although then fill in hospital out-patient details.
- Ask dates of sick notes.
- For prescription medication section add strength, amount, if repeat medication, when started taking the medication and how many repeat prescriptions were filled in past X months.
- The question on ‘Do you pay for prescriptions?’ could be re-located after over the counter section. A box for ‘how much have you paid for your prescriptions over the past X time?’ is also needed.

For medical extraction questionnaire:

- Could add common GP tests or else have two separate sections, one for hospital tests and the other for GP tests. GP tests section should have about 20 rows.

Comparison of GP medical records to participant questionnaires

In designing a larger study, we wanted to know the relative merits of collecting resource data from participant questionnaires alone, from medical records alone or from both. To explore this, we decided to compare GP medical records and questionnaires for for two domains: GP consultations and medications. We chose these two areas based on the assumption that GP medical records would be more robust for GP consultations and participant questionnaires might be more accurate for medications.

We selected 28 participants – all 19 control participants and their nine matching cases. However, a major difference was that GP medical record data covered a two year period, while participant questionnaires could suffer from gaps due to late or missing returns. Sometimes participants did not date their questionnaires (these were excluded from the analysis) and occasionally participants would send in questionnaires where the time period overlapped. Thus, participant questionnaires provided snapshots in time while GP medical records are continuous.

Table 2 Comparison of GP medical records and participant questionnaires for recording of GP consultations

Participant	Number PQs missing	Potential overlap of PQ time period	GP F2F consultation (GP telephone consultation)		Difference (PQ-MR)
			PQ	Medical records	
6	none	yes	11	5	6
10	one	yes	6	7(1)	-1(-1)
14	none	no	7	3	4
21	none	no	3	2	1
22	none	yes	3	10	-7
23	none	yes	3	3	0
24	none	yes	10	3	7
25	none	yes	5	4(1)	0
26	one	no	3	3(2)	(-2)
35	one	no	16	11(6)	(-1)
36	none	yes	12	5	7
39	one	yes	5	6	-1
42	three	no	3	5(2)	-2(-2)
47	none	no	6	4(1)	1
49	none	yes	9	7(2)	0
51	two	yes	4	3	1
52	none	yes	5	2	3
55	two	no	1	1	0
56	one	no	1	1	0
475	one	yes	2	3	-1
158	none	yes	11(3)	6	5 (3)
882	none	yes	2	3	-1
891	none	yes	6	5(1)	1
902	none	no	15	10	5
939	one	no	2	2	0
975	none	yes	3	2	1
985	none	yes	4	2	2
064	none	yes	9	17(5)	-8

The results from this table suggests that given the number of participant questionnaires that are missing and overlap, relying on participant questionnaires to provide continuous data over several time points would be inadvisable.

There are substantial variations in the recording of GP consultations between GP medical records and participant questionnaires. If the GP record is held as more robust, participants appeared to overestimate their resource usage or their questionnaires double counted in 13 cases. In nine cases, there was an underestimate of GP consultations. There was agreement between the two sources for only six of the 28 participants. All of but one of these six participants had a small number of consultations (five or less), although there were discrepancies between the two sources for other participants with similarly low levels of consultations. Telephone consultations often appear overlooked, which concurs with qualitative data.

For the analysis of medication data, one participant was dropped as the medical records stated ‘see notes’ which were not available in time for this analysis.

Table 3 Comparison of participant questionnaires and GP medical records for the recording of medications

Participant	Additional in PQ	Additional in Medical records
6	none	chloramphenicol benzydamino hydrochloride
10	prochlorperazine	diclofenac
14	none	none
21	none	none
22	none	flucloxacillin prochlorperazine ciprofloxacin diclofenac
23	none	influenza injection erythromycin
24	none	none
25	none	Scheriproct
26	"eye cream"	none
35	none	temazepam fluconazole levothyroxine econazole nitrate
39	none	cocodamol amoxicillin proctosedyl lactose solution
42	none	none
47	none	influenza injection codeine phosphate diclofenac sodium
49	none	etericoxib diclofenac paracetamol co-amoxiclav
51	none	crotamiton vagifem cetirizine hydrochloride
52	paracetamol	penicillin
55	none	none

Participant	Additional in PQ	Additional in Medical records
56	none	none
475	none	none
158	aciclovir zincum (homeopathic) something unnamed for 'general problems'	xylomazoline amitryptiline depo-provera medroxyprogesterone fluconazole trimethoprim
882	aromasin (anmisin?)	nitrofurantoin trimethoprim omeprazole viepax pandemrix
891	cold sore cream glandular fever nosode epstein barr (hom?) falco peregrinus	prase odymium bromatum aurum bromatum citalopram hydrobromide
902	calc mur cuprum muriaticum augmentin proteus lac caninum	goserelin implant co-amixiclav phst elvarex dress flu vaccine cortisone
939	beclometasone	tungstenium metallicum molybdenum muriaticum
975	none	methylprednisolone injection
985	bisoprolol arsenicum	aconite argentum nitricum
064	none	serenity cream estriol invag chloramphenicol mometasone furoate cetirizine hydrochloride sodium cromoglycate st john's wort caps

The results from this table suggest that there was full agreement between participant questionnaires and GP medical record data in seven of the 27 cases. Participant questionnaires tended not to include details on medications such as antibiotics, contraception, influenza and other injections, pain relief and sometimes homeopathic remedies prescribed by the Bristol Homeopathic Hospital physician. Medical records tended not to include details on homeopathic remedies and medications that could be obtained over the counter, but were actually prescribed.

Key learning points

- Maximising personal contact between the study team and the participants is helpful, so ringing, e-mailing or texting participants to ask for return of questionnaires worked well.

- Monitoring the administration of the questionnaires through an Access database was helpful. Ideally, data from questionnaires should be entered as soon as possible after receipt.

- The process of extracting GP medical record data was time consuming and laborious but yielded a rich quantity of information on NHS service usage, some of which was not obtainable via participants (e.g. laboratory tests).

- Data cannot be directly extracted from GP medical records and input into a study database as considerable time is needed for checking and cross checking information across the records and then between the records and the participant questionnaires. For this reason, obtaining copies of the medical records is advisable.

- The data from GP medical records that appear to be robust and trustworthy are:
    - GP and practice nurse consultations
    - Hospital out-patient consultations delivered by a doctor
    - Minor injuries unit
    - Hospital in-patient admissions
    - Hospital tests with documented results
    - Laboratory tests

- Prescription data from GP medical records was surprisingly not that trustworthy. Medications prescribed by hospital consultants were often not listed in GP medical prescription charts while repeat medications prescribed by GPs sometimes were also left unrecorded.

- GP medical records for community clinics and non-doctor hospital visits were often incomplete. This could be picked up more explicitly in the participant questionnaires.

- Both the participant questionnaire and the GP medical record extraction tool should be revised before carrying out a larger study.

- Given the overlap and gaps, relying on participant questionnaires to provide continuous data over several time points would be inadvisable. Only GP medical record data can provide continuous information over a study period.

- Ideally, both participant questionnaires and medical record extraction should take place to ensure more accurate collection of NHS service usage. Neither source on its own provides a complete picture. The advantage of drawing on both sources is that some queries can be resolved, although occasionally discrepancies also emerge.

Part II Quantitative component

Quantitative results

Quantitative methods

The economic evaluation was carried out from the perspectives of both NHS and societal costs. Data on NHS service usage was collected from GP medical records for both cases and controls using the index data of the first appointment for the case participant at Bristol Homeopathic Hospital. Records for the 12 months before that index date were classified as ‘baseline’ (2009) and records for the year during the intervention were classified as ‘intervention’ (2010). In addition, all cases and controls completed wellbeing and quality of life questionnaires every 3 months from baseline (a total of 5 time points).

NHS services measured included:

- all primary care contacts
- diagnostic tests
- outpatient appointments
- inpatient hospital stays
- prescribed medicines
- intervention costs (ie homeopathic package of up to five consultations per annum)

Service use was extracted from the medical record because the GP medical records were assumed to be more accurate than patient recall over a 3 month period for most. Overnight hospital stays were the only NHS service to be based on self reported usage, due to between practice variations in the recording of secondary care use within GP medical records. Costing of contact with health professionals in primary care used PSSRU reference costs (www.pssru.ac.uk) and laboratory diagnostic tests were based on unit costs reported from private communication with a laboratory director (Waltersdorf 12 January 2012). The NHS Reference Costs 2009-10 was used to cost secondary care services (www.dh.gov.uk) and drug costs were based on the British National Formulary (www.bnf.org).

Personal costs were collected through the participant questionnaires and were all self-reported. They included all health-care associated travel, privately funded treatment, care within the home, domestic help, over the counter medicines and time off work. Since self-reported service usage (chiropractic, physiotherapy, counselling, occupation-therapy and psychiatry) did not differentiate between NHS funded and privately purchased services, all services with reported costs were assumed to have been privately purchased. Missing self reported resource costs were multiply imputed (20 iterations) based on age, gender and case/control status.

Summary statistics were used to compare cases and controls. Descriptive analysis of normally distributed continuous variables was based on means and standard deviations (SD), and medians and inter-quartile ranges (IQR) use for skewed variables. Continuous variables were compared using Mann Whitney U test and Student's t-test. Differences were considered statistically significant at P <0.05.

Mean (Thompson et al. 2000) NHS and societal costs for cases and controls were compared for the 12 months prior to (2009) and following the baseline (2010) and the significance of the differences examined. Societal costs were only recorded for the 3 months prior to baseline but to aid comparison between NHS and societal costs, these were expressed as costs per annum.

To perform a cost utility analysis of the service, Quality Adjusted Life Years (QALYs) were calculated based on the five time points at which the SF-36 was administered. A subset of the SF-36 questions was used to populate the SF-6D [Brazier *et al.* 1998]. The SF-6D is based on 11 items of the SF-36, which are used to generate the 6 dimensions of the SF-6D. These dimensions consist of three physical (physical, role and pain) and three mental (social, mental and vitality) components. The contribution of these components to observed changes over time were explored by calculating the mean decrease in patient health from "perfect health" attributed to the respective components.

Only individuals with both baseline measures and at least one measurement in both the first and second half of the 12 month follow-up were included in the analysis. Missing values were imputed (20 iterations) and QALYs calculated using "area under the curve" values, adjusted for initial differences between cases and controls by regression on baseline values. To check for consistency in the changes of quality of life seen in the SF-6D scores of cases over that of controls, we looked at changes in the Warwick-Edinburgh Mental Well-being Scale (WEMWBS). The WEMWBS questionnaire consists of 14 questions, the scores of which are combined to a single score and higher values indicate better mental well-being.

To assess whether the service should be adopted the Net monetary benefit (NMB) based on NHS costs was calculated with a willingness to pay threshold set at £30,000 per QALY. (www.nice.org.uk)

Net monetary benefit is calculated by assuming a willingness to pay threshold, then converting health benefits (QALYs) into the common metric of pounds. The cost associated with a treatment strategy is then subtracted, resulting in the net benefit of this strategy in monetary terms.

Net montetary benefit = (E*WTP)-C

E=effectiveness; WTP=willingness-to-pay-threshold; C=cost

A sample size calculation was performed to estimate the study population required to detect a significant difference in the NMB of providing the service for the larger study. Sample size calculation was based on an assumption of equal SD in effects and cost between cases and controls, and a 90% probability ("power") of rejecting the null hypothesis, that the difference in NMB is 0, when it is false.

All analysis was carried out using STATA 11 by an independent statistician.

Quantitative results

Sufficient quality of life and costs data was available at baseline and during follow-up for 9 cases and 17 controls. The cost analysis was restricted to this subset of individuals.

Resource utilisation

Table 4 Resource Use in Cases and Controls 12 months prior to and post baseline

	Cases (9 individuals)		**Controls (17 individuals)**	
	2009	**2010**	**2009**	**2010**
NHS				
Primary Care				
Contact: GP (face to face) (2)	4 (2, 10)	2 (0, 17)	4 (0, 17)	4 (1, 9)
Contact: GP (phone) (2)	1 (0, 5)	0 (0, 4)	2 (0, 10)	0 (0, 6)
Contact: Practice nurse (2)	2 (0, 4)	1 (0, 3)	1 (0, 8)	2 (0, 9)
Contact: Practice nurse (phone) (2)	0 (0, 2)	0 (0, 0)	0 (0, 1)	0 (0, 2)
Contact: District nurse (2)	0 (0, 1)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Contact: Physiotherapy (2)	0 (0, 2)	0 (0, 4)	0 (0, 3)	0 (0, 2)
Contact: Osteopathy/Chiropractic (2)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 1)
Contact: Community Mental Health (2)	0 (0, 0)	0 (0, 0)	0 (0, 1)	0 (0, 1)
Secondary Care				
Number of A&E visits (2)	0 (0, 1)	0 (0, 0)	0 (0, 3)	0 (0, 1)
Number of Outpatient visits (2)	2 (0, 11)	1 (0, 9)	0 (0, 6)	0 (0, 4)
Number of Admissions (2)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 1)
Other				
Number of prescriptions (1)	4 (0, 5)	7 (5,10)	5 (1,10)	5 (3, 7)
Number of Tests (1)	7 (1, 8)	2 (1, 5)	3 (0, 9)	5 (0, 10)

KEY:	
Median (IQR)	1
Median (maximum and minimum values)	2

Note: Table 4 only records events occurring more than once during the study period.

From this table, we can see that for cases the mean number of GP contacts, practice nurse contacts and number of tests decreased for cases while they either increased or stayed the same for controls, although the sample size is small with substantial variability. The exceptions are out-patient visits, which were understandably greater for cases as this included visits to the homeopathic hospital out-patient department, and prescriptions where the mean number of prescriptions for cases increased from 4 to 7. The mean number of prescriptions remained constant for controls. For all variables, the maximum and minimum values are wide, suggesting considerable variability between individuals in both the case and control populations.

Costs

Table 5. Mean (SD) NHS and Personal Costs for Cases and Controls 12 months prior to and post baseline.

	Cases n=7		Controls n=17	
	Baseline	**Intervention**	**Baseline**	**Intervention**
NHS				
General Practice	£ 627 (381)	£ 463 (394)	£ 599 (432)	£ 480 (372)
Other primary care	£ 13 (40)	£ 28 (60)	£ 18 (51)	£ 77 (258)
Prescribed medication	£ 34 (48)	£ 88 (143)	£ 65 (88)	£ 49 (78)
Secondary Care	£ 350 (411)	£ 259 (405)	£ 216 (302)	£ 432 (975)
Total	£ 1025 (607)	£ 839 (842)	£ 899 (743)	£ 1039 (1481)
Personal (8% imputed)				
Private therapy	£ 25 (57)*	£ 56 (111)	£ 36 (102)*	£114 (343)
Non-prescribed Medications	£ 133 (198)*	£ 288 (433)	£ 143 (250)*	£187 (304)
Travel	£ 13 (39)*	£ 18 (46)	£ 1 (4)*	£1 (2)
Loss of earnings	£ 1940 (3224)*	£ 802 (2653)	£ 420 (1162)*	£80 (590)
Domestic help/childcare	£ 533 (1600)*	£ 0 (0)	£ 0 (0)*	£0 (0)
Total	£ 2644 (3274)*	£ 1164 (2710)	£ 600 (1165)*	£ 383 (745)

KEY:

*	figures estimated from the 3 months prior to baseline

Table 6 Comparison of Case and Control Participants for Mean difference in NHS and Personal Costs

Comparison	NHS Costs	Personal Costs
	Mean difference (95% CI, p-value)	Mean difference (95% CI, p-value)
Controls: baseline-intervention	£ -140* (-724 to 444, p=0.618)	£ 217 (-74 to 510, p=0.1.34)
Cases: baseline - intervention	£ 186 (-169 to 541, p=0.261)	£ 1480 (-468 to 3427, p=0.175)
2009: control-case	£ -126* (-692 to 440, p=0.648)	£ -2043* (-4590 to 503, p=0.104)
2010: control-case	£ 201 (-741 to 1142, p=0.664)	£ -781* (-2878 to 1316, p=0.419)*

*Mean differences are negative when costs are higher in the cases.

At entry to the study, cases had higher mean NHS and personal costs compared to controls, £126 and £2043 respectively (see table 6). In the intervention year cases also had a £781 higher mean personal costs in the intervention year but £201 lower mean NHS associated cost compared to controls. None of these differences were significant.

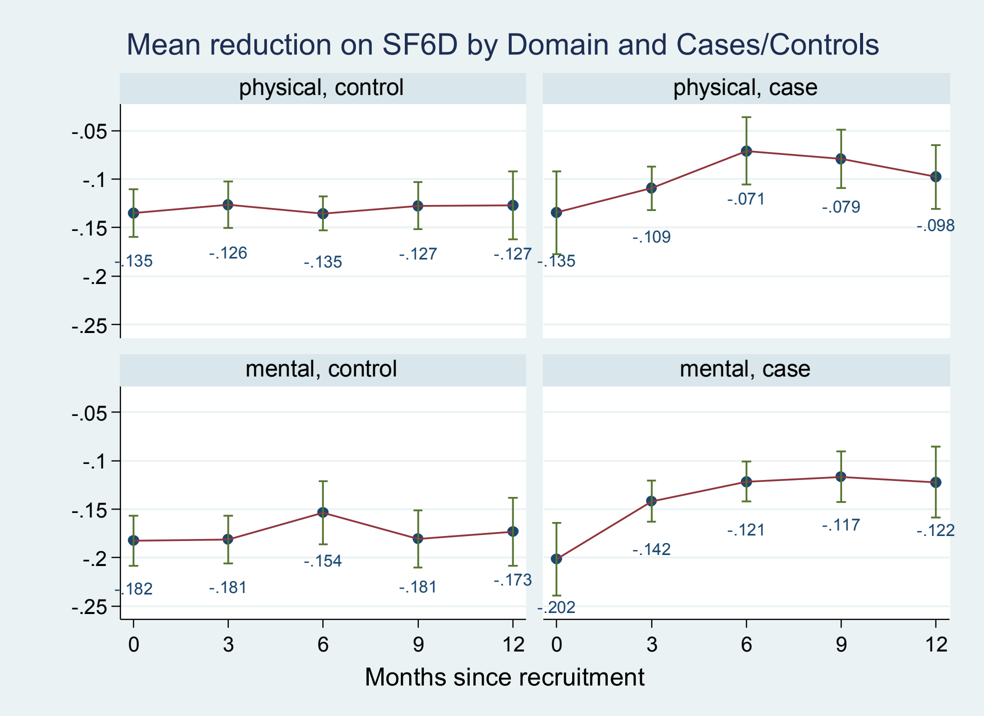
Quality of life

In the 12 months following recruitment to the study. cases had a better quality of life (0.733 [95% CI: 0.712, 0.754]) compared to controls (0.650 [95% CI: 0.600, 0.701]) [p value=0.056]. This was a difference resulting from change during the study since baseline cases (0.610 [95% CI:0.498, 0.721]) and controls (0.624 [95% CI: 0.567, 0.680]) had very similar SF-6D scores (p value= 0.783).

Figure 2 Divergence in SF-6D scores over the study period.

This marked improvement in SF-6D scores in cases during the study is primarily due to improvements in the mental health domain. 68.3% of the increase in the overall score between baseline and 12 months is due to increases in the mental domain. Figure 3 illustrates the changes in the mean decrease from “perfect health” attributable to the physical and mental domains of the SF_6D score in cases and controls over time.

Figure 3 Changes in mean reduction on SF6D by domain for case and control participants



To investigate this further, we compared the wellbeing scores of cases and controls and found a similar pattern of improvement amongst case participants compared to controls.

Figure 4 Changes in wellbeing overtime for cases and controls

Between baseline and 12 months controls showed no significant improvement in WEMWBS scores (p value= 0.657), whilst cases showed a significant (p value = 0.007) increase in the mean scores of 11.3 points.

Net Monetary Benefit

A ceiling cost per QALY of £30,000 corresponds to a Net monetary benefit of £3118 (95% CI: 445, 5791), which significantly differs from zero (p value = 0.016). The interpretation of NMB is that if all else is equal, interventions should be adopted where the NMB is greater than zero. This is because the incremental cost effectiveness is less than the ceiling ratio i.e. it costs less than £30,000 per QALY gained. However given issues with the matching of cases and controls, caution should be taken when interpreting the significance of this result.

Sample Size Calculation

A sample size calculation was performed based on the observed difference in mean NHS costs (-£200.56) and QALYs (0.097) between cases and controls, the observed variation in NHS costs (SD=1197) and QALY gained (SD=0.034) during the intervention year, and and the observed correlation between the differences in costs and QALYs gained (-0.158).

With a ratio of one-to-one for cases-to-controls a total sample of 45 in each category would be required to have an 90% chance of finding a significant ($p < 0.05$) variation in NMB (assuming a ceiling ration of £30,000 per QALY) from zero.

Discussion of quantitative findings

The main findings from this feasibility study from the quantitative analyses are:

- At baseline, costs were higher for case participants but not significantly so.
- Cases and controls were well matched for both quality of life and wellbeing at baseline.
- There was no significant difference in resource utilisation in the 12 months after baseline between cases and controls.
- Individual variability in resource utilisation for both cases and controls was substantial.
- Despite the lack of significant change in resource utilisation, cases reported a significant improvement in quality of life and wellbeing compared to controls over the 12 month study period. The largest change in quality of life was scored in the domains of mental health.
- Assuming that this is a fair comparison between cases and controls and taking both quality of life and cost data into consideration, the significant net monetary benefit ratio suggests that the intervention of homeopathic packages of care should be adopted.
- If these results were to apply to other homeopathic case and matched control populations, then 90 participants (1:1 matched) would be needed in a larger study to demonstrate that the quality of life and wellbeing improvements generated by homeopathic packages of care are worth their cost.

However, there are important limitations to this study which mean that these results should be taken with caution. For example, the matching of cases and controls is somewhat dubious. Unlike randomised controlled trials, neither the case nor control participants were selected randomly. In this prospective controlled cohort design, the nine homeopathic hospital case patients were derived from an initial sample population of 315, and so these nine are unlikely to be representative of the wider Bristol Homeopathic Hospital population. To find matching controls, a non-clinical researcher, with the assistance of mainly administrative GP surgery staff, identified and selected potential controls on the basis of GP practice, sex, age within five years and condition. Although the first three matching criteria were tightly defined, matching for condition was considerably more challenging. Of the eight matched pairs for whom we collected qualitative data which explored detailed health history information, only five matches were assessed as ‘good enough’ by three independent clinicians who believed that both symptoms and condition were appropriately matched. Thus, with this study population of cases and controls, we might not be comparing like with like. If there was a better comparison between the case and control groups, then probably a larger study sample would be needed to see a significant effect. Given these limitations, it would be unwise to design a future study with only twelve people.

Nonetheless, these results do suggest a significant improvement in quality of life and wellbeing for case participants compared to their controls.

So key questions raised by these results are:

1. Why are the quality of life and wellbeing scores so much better for the cases than the controls?
2. Is the improvement in quality of life and wellbeing scores attributed to homeopathic treatment by case participants?

To explore this, we turned to the qualitative interview data with seven of the nine homeopathic cases and eight of their 17 controls.

In discussing the wellbeing and quality of life questionnaires, all respondents questioned stated that the changes (or lack of change) recorded in these two questionnaires over 12 month intervention period accurately reflect their perceptions of changes or stasis in wellbeing and quality of life. However, several case participants stated that modifications in wellbeing and quality of life were more attributable to family difficulties (e.g. bereavements, lost jobs, teenage children) or acute major illnesses (e.g. two case participants had cancer treatment during the baseline year) than to the condition. However, control participants were more likely to mention that they completed the questionnaires in relation to their condition. So perhaps the quality of life and wellbeing scores for the case participants improved significantly not because of their homeopathic treatment, but because they were less subjected to major life disruptions during the intervention year.

Alternatively, in looking at the accounts of the case and control participants more closely, what becomes apparent is that although they were matched for the same presenting symptom (usually hot flushes), the control participants were more likely to suffer from chronic pain, anxiety and/or depression (6/8) than case participants (1/7). Therefore, another possible explanation for the significant improvement in wellbeing and quality of life scores is that the control participants were more likely to have multiple and more severe conditions. However, given that the baseline scores for wellbeing and quality of life were comparable between case and control participants, this explanation is not entirely satisfying.

A further explanation could be provided by exploring the impact of homeopathic treatments and consultations on condition, quality of life and wellbeing. In turning to the qualitative data, in assessing the impact of homeopathic treatment on their condition of the seven case participants interviewed, two believed homeopathy did not help, two are not sure, two believed homeopathy helped in some way and one was categorically certain that homeopathy had made the difference. Thus, there is substantial uncertainty about the impact of homeopathic treatment on their condition.

However universally in the interviews, participants mentioned valuing the listening and questioning skills of the homeopathic physician. Many commented that these had given them new insight into longstanding difficulties, including family situations and managing stress. It is entirely possible that these new ways of thinking and managing problems might have had an impact on wellbeing and quality of life, and several participants did make this link explicitly. As we only asked if homeopathic treatment had impacted on condition, not on wellbeing or quality of life, we cannot be more conclusive. But given that homeopathy is a holistic, person centred treatment, it could be argued that the changes in quality of life and wellbeing could be attributed to homeopathic treatment. To investigate this further, future research should explore the impact of homeopathic treatment on quality of life and wellbeing.

Part III Feasibility and attributes

Feasibility of study methods and tools and attributes

Qualitative methods and methodology

Aims

The qualitative component of this study had five main aims:

1. To gather information on participants' experiences of taking part in the study and ways it could be improved.
2. To explore the degree of 'matchedness' between Bristol Homeopathic Hospital cases and their community controls to identify the matching criteria for a larger study.
3. To gauge the feasibility, acceptability and sensitivity of the outcome measures (Warwick-Edinburgh Wellbeing tool, SF-36 and the Client Service Resource Inventory).
4. To identify characteristics of value to Bristol Homeopathic Hospital service users as the first step in developing a stated preferences discrete choice model.
5. To understand the decision-making behind study participants' use of homeopathic and/ or conventional services and the ways in which they access services.

The rationale for this last aim was to explain and add richness to the quantitative findings of the study by providing an understanding of why and in what ways participants might (or might not) be reducing their use of healthcare services.

We chose semi-structured qualitative interviews to obtain the relevant data because they are flexible enough to capture the individual concerns of each participant, yet sufficiently comprehensive to ensure that we collected data to address all of our aims. We also wanted in-depth data to better understand the circumstances, trajectories, options and ways in which people make decisions around healthcare service usage.

Sampling

To address these aims, we needed a sample that included both case and community control participants. We sampled purposively on the basis of maximum diversity, to gather a range of views.

For the sampling frame, the 45 participants in the study were broken down into:

- 19 community controls
- 26 Bristol Homeopathic Hospital participants sub-divided into:
    - 9 matched with one or more community participant
    - 4 that did not give permission to view their records
    - 7 where the GP surgery did not give permission to view medical records

  - 6 where permissions were obtained but either no controls were identified or no controls accepted the study invitation

We wanted to gather the views of participants from all of these sub-categories, but our priority was to learn more about the experiences of matched cases and controls so we over-sampled from this group. All nine matched Bristol Homeopathic Hospital participants were invited to interview, of which eight accepted. We attempted to contact the ninth case, who was a travel photographer, several times without success. We also wanted at least one community control for every case.

In selecting candidates for the other sub-groups (community controls and non-matched cases), we had several other considerations. Given the low proportion of non-White participants in the sampling frame and the difficulties in accessing their views, all four were invited to interview, of which two took part. Other sampling criteria were:

- Low/ high returners of questionnaires
- Frequent/ infrequent NHS service user

High returners of questionnaires returned all five, while low returned three or fewer.

Frequency of service use was calculated for both baseline and intervention years for those with medical records. The classifications for frequency of service use were:

- high (15 or more annual GP contacts and distinct prescriptions)
- medium (6-14 annual GP contacts and distinct prescriptions)
- low (5 or fewer annual GP contacts and distinct prescriptions)

Where we did not have access to medical records, frequency use was calculated from the last four participant questionnaires which roughly covered the intervention year only. Our sample aimed to include a range of participants from high, medium and low groups.

In addition, we gave preference to those candidates who appeared to have trouble in completing the questionnaires and those Bristol Homeopathic Hospital participants whose medical records showed that they had reduced service usage over the study period. We also wanted to ensure a mixture of urban and rural residents.

Eleven community controls were invited into the study, of which nine accepted. None of the community controls matched with 891 accepted our invitation to interview. In contrast, two community controls matched with 882 accepted our invitation and both were interviewed. So this resulted in seven Bristol Homeopathic Hospital participants matched with eight community controls, which gave eight matched case-control pairings.

Of the four Bristol Homeopathic Hospital participants who did not give permission to access their medical records, three were interviewed. We also interviewed three Bristol Homeopathic Hospital participants whose GP surgery refused permission. Our final candidate was selected because her GP and her medical homeopath was the same practitioner and we wanted to learn more about how this influenced her NHS service usage.

In total, 23 interviews were conducted, 14 with Bristol Homeopathic Hospital participants and 9 with community controls.

Data collection

Candidates were selected and invited by telephone or e-mail to take part in an interview and a date was arranged. At the appointed time prior to interview, the interviewer administered consent, although written consent for interview had already been given at the time of the recruitment. The interviewer reminded the participant that the interview would be recorded, the transcript would be anonymised and any quotes used would be unattributable. The participant was also informed that s/he could withdraw their interview data wholly or partially from the study at any time.

The topic guide was drawn up in consultation between LW and Elizabeth Thompson, lead clinician at the Bristol Homeopathic Hospital. The three areas of questions were: 1) feedback on the questionnaires and the study, 2) healthcare decision-making and 3) experiences of the Bristol Homeopathic Hospital (case participants only). The topic guide was reviewed about halfway through data collection whereby a few adjustments were made such as the inclusion of a question on relationship to health. A copy of the topic guides for Bristol Homeopathic Hospital and community participants are included in the appendix (see Appendix D and E).

Because this was a feasibility study, participants were offered a choice of telephone or face to face interview, although for some candidates who lived a long distance from Bristol, only telephone interviews were feasible. In total, twelve interviews were by telephone and eleven were face to face.

The length of the interviews ranged between 20-80 minutes. The interviews were conducted by two researchers, LW (n=6) and Lorna Duncan (LD) (n=17), and took place from April – October 2011. As LW was offering supervision to LD, LW regularly reviewed the transcripts and passed on suggestions to LD through e-mail, telephone and face to face meetings. A member of the steering group (Elizabeth Thompson) independently assessed a sample of interview transcripts for quality and found that: 1) there was little difference between telephone and face to face interviews and 2) the quality of interviews conducted by LD was good. All interviews were recorded and transcribed by an experienced independent transcriber.

Analysis

To re-cap, broadly speaking the aims of the qualitative interviews were:

1. to gather views on the study design, methods and outcome tools to inform a larger study
2. to identify attributes for a discrete choice model
3. to explore decision- making around use of healthcare services

4. To assess the level of ‘matchedness’

Accordingly, the data were analysed in different ways.

To analyse views on the study (aim 1), we used two analytical approaches: framework and content analysis. As this was a feasibility study, we wanted to compare and contrast the two approaches, which varied in their level of inductiveness, to find out the advantages and differences in the two methods.

For the more deductive, top-down framework analysis, LD constructed an Excel spreadsheet with five domains:

- reasons for accepting the study invitation
- recruitment and retention
- questionnaires
- ways to improve the study
- other key issues/ concerns

LD read each transcript for all 23 interview participants and transferred quotes and data for each participant into the appropriate domain cell. She then read all the data for each domain across the cells and summarised the key findings in five separate documents. In addition, she drew together a document detailing the characteristics of the interview participants.

For the more inductive content analysis, LW created an independent document and transferred any quotes from the transcripts relating to the study design, methods or questionnaires. These quotes were then coded and classified into 18 different domains according to content e.g. feedback on wellbeing questionnaire, problems in questionnaire administration, what wasn’t recorded etc using NVIVO. Each domain was read and then summarised, key issues and responses were identified and conclusions drawn.

To identify the variables for a discrete choice model (aim 2), LW used inductive content analysis again. Data relating to what was valued and less helpful were extracted in their entirety from transcripts as part of the process of developing summaries for each of the 14 Bristol Homeopathic Hospital participants. These extractions were collected in one document and amalgamated across all 14 Bristol Homeopathic Hospital participants, read and coded. These codes were then classified into two domains: what values and what is not helpful. Within these two classifications, the codes were further broken down into those relating to the service (e.g. location, timing of appointments) and those relating to the treatment (e.g. positive benefits, style of practitioner). In this way, the following attributes were identified.

Analysis to meet the third aim of exploring decision making around healthcare service usage required a different tact. While conducting the interviews, the researchers gleaned that context is crucial to understanding healthcare decision making. Therefore approaches like content, thematic and framework analysis, whereby the data are segmented, separated out and stripped of context, did not seem appropriate. Given that the interviews were semi-structured to ensure that data for aims 1 & 2 were collected, narrative analysis was also not an option as the interviews were too directed by the researchers.

Instead, LW took an approach whereby each of the 23 interview participants was a 'case'. To develop an understanding of each case, LW drew on interview data, medical records and participant questionnaires to create an individual summary. Each summary document contained the headings of:

- Overview (ie participant characteristics)
- Synopsis
- Resource usage (ie what they consumed)
- Decision making (ie why they consumed particular resources)
- What made a difference
- Relationship with GP

She read through each interview transcript and cut and pasted relevant quotes under these headings. While carrying out this process, she also used the 'comment' function to note down ideas, reflections and queries. In addition, she listened to all or sections of the sound files recorded when the interview took place. Where appropriate, LW consulted the medical records and participant questionnaires, for example to check reasons for GP visits or names of medications (medical records) and types and number of over the counter medications used.

For the overview section, LW recorded details from the participant questionnaires such as sex, age, marital status, job, income, accommodation, place of residence and total number of questionnaires returned. From the medical records, LW tallied number of annual GP contacts and different types of prescriptions at baseline and intervention years.

Once summary sections (except for synopsis) were complete, LW read through the summary document to identify key points, compare stated behaviour with actual behaviour and puzzle out the answers for three key questions:

- How does this participant consume healthcare resources?
- What resources does this participant consume?
- Why does this participant consume these resources?

Thus, although a range of data was drawn on to support conclusions, a highly interpretative approach was taken. Therefore, others accessing these same data may come to a different understanding.

After all 23 summaries were completed, LW pulled together packs of five summaries (2 matched pairs and one unmatched case participant) for separate discussions with an independent qualitative colleague and a member of the steering group (ET). To analyse the data further and gain greater understanding of how and why participants accessed and utilised healthcare resources, LW carried out several comparisons including:

A. High versus medium versus low resource users
B. Bristol Homeopathic Hospital participants versus community controls
C. Matched pairs
D. Those who change level of resource usage versus those who do not
E. Conditions (e.g. all women with menopausal symptoms)
F. Those who have asked their GPs for particular services versus those that have not initiated requests

To meet the fourth aim, the overview and synopsis for seven matched case and control pairs were pulled together into one document. This document was then sent to the steering group, which included three clinicians – two academic GPs and a consultant homeopath. They were asked to rate the degree of matchedness separately for each pair from 1 (poor match) to 3 (excellent match). They were also asked to reflect on the key criteria for identifying good matches. These independent responses were then discussed at a steering group meeting and reported in the 'comparability' section of this report.

Interview participant characteristics

As stated previously, 23 participants were interviewed for this study: 14 from Bristol Homeopathic Hospital and eight from the community. Participants were chosen using the sampling criteria below.

Table 7 Sampling criteria for interviewed participants

Participant sub-group	**Candidate**	**Urban/ rural**	**Number of Qs returned**	**Level of resource use**
Matched case				
	475	Urban	4	Low
	882	Rural	5	Medium/high
	891	Urban	5	Medium/low
	902	Urban	5	High
	939	Rural	4	Medium
	975	Rural	5	Medium
	985	Rural	5	Low
	064	Rural	5	High
Community control				
	6	Rural	5	High
	10	Rural	4	High
	14	Rural	5	High
	21	Rural	5	Medium
	26	Urban	4	Low
	35	Rural	4	High
	47	Urban	5	Medium/high
	52	Urban	5	Low/ medium
	55	Rural	3	Low
Unmatched case				
	158	Rural	5	Medium
	974	Rural	5	Medium (PQ)
	919	Urban	5	Low (PQ)
	987	Rural	5	Low (PQ)
	073	Rural	5	Medium (PQ)
	113	Rural	5	High (PQ)

Of the 23 selected participants, two were men (one Bristol Homeopathic Hospital and one community) and the other 21 were women. Participants ranged in age from 39-75. The 75 year old was 15 years older than the next oldest participant. Fifteen were married; five were divorced and three were single. Thirteen had from one to eight children, although the most common number of children was two (8 participants).

Two were British Asian. Several other participants had non-UK backgrounds as one came from Holland, another from Columbia, a third from Norway and a fourth from France. The Norwegian and French participants had both used homeopathy before coming to the UK.

Although professions are not known for all 23 interview participants, eight had professions related to healthcare including a retired GP, a nurse, a midwife, a homeopath, a dentist, a psychotherapist, a consultant and a hospital chaplain. Other professions included school lunchtime supervisor, financial accounts manager, personal assistant and engineer. Two participants were housewives and two were in education, one of whom was a deputy head. In addition to the GP, two other participants were retired.

Few people gave information on their income. Of those that did, five earnt under £10,000 annually; two earnt between £10-£15 thousand annually; two earnt between £25-£30 thousand annually; one earnt between £30-£35 thousand and one earnt £50 thousand plus. Two participants were on incapacity benefit. Thirteen participants owned their own homes; four rented accommodation and two lived in council or housing association residences.

By far the most common condition for matching amongst the female interview participants was hormonal related symptoms caused by the menopause (8) and breast cancer treatments (2). One woman had endometriosis. Other conditions that women suffered include fatigue (2), palpitations (2), low mood (2) digestive problems (1), recurrent viruses and stress (1), mood swings (1) and eczema (1). One male participant had knee pain and the other arthritis. In addition to these conditions, most participants had other conditions such as digestive problems, thyroid conditions, headaches, back pain and so on, many of which were much higher priority than their matching condition.

Only one person had not used any form of complementary medicine – this was the male community control with knee pain. All other participants have used one or more CAM therapies, whether this was over the counter preparations or consultations with CAM practitioners.

Results on feasibility

Methods

An aim of this feasibility study was to assess the study design, recruitment methods, ways to sustain involvement and outcome tools (ie rate of return, acceptability, sensitivity to change, appropriateness, completeness). This section provides findings from questionnaires from all 45 study participants, from the medical records of 34 participants and 23 qualitative interviews, fourteen with BHH participants and 9 from GP practices. The qualitative interviews were analysed independently, as outlined previously, and then researchers drew on the questionnaire and medical record data to confirm findings.

Recruitment to the study

Because of the ethical considerations, postal invitations issued from GP surgeries appear to be the default recruitment method for community controls. But we did explore alternative ways to recruit BHH participants to improve uptake rate.

Several BHH participants said they were happy with postal recruitment. One said she preferred face to face as a more personalised approach.

> *Um I think it would have been better, because it's more personal. So um I mean either way, if I knew there was something I could do to support homeopathy, I'd be doing it. But I think (being personal) is a lot more personal and a nicer way.* (participant 891)

Possible ways of a more personalised approach suggested by the interviewers were:

1. Researcher on site at first appointment

2. Recruitment through homeopathic physician at first appointment

All three of the participants who considered the first option rejected it, with one saying it would be too "grabbing". For the second option, two thought recruitment through the homeopathic doctor would be fine, with one mentioning that she had been recruited to a different homeopathic study this way.

> *...there has actually been another thing being done at the homeopathic when I first started, recording on a scale how you actually felt about the treatment....So I mean I was recruited by the homeopathic doctor for that and, you know, that was fine.* (Participant 475)

Another Bristol Homeopathic Hospital participant suggested a third way in which the secretaries at Bristol Homeopathic Hospital would hand out the invitation, information sheets and questionnaires at the first appointment, so that participants could fill them in while they were waiting. She had been recruited to a different hospital study in this way and was happy with this recruitment method.

Reasons for taking part

Many BHH participants took part because they saw the BHH under threat and/or wanted to support homeopathy in the NHS.

> *I don't want to see an end to the homeopathic services, and anything that can show that it's doing some good is a good thing… because there are so many conditions that can't be helped conventionally, aren't there, that can be helped homeopathically?* (participant 985)

> *Um it's because, from what my GP said, "Oh they're going to close the homeopathic hospital." And I actually believe in homeopathy.* (participant 975)

However wanting to support NHS funding of complementary therapies also influenced at least one community control.

> *I think the main reason is I did, I've got a postgraduate diploma in health promotion so I know a bit about surveys and anything that might help people to get a bit of funding for complementary medicine with long-term health conditions is fine by me because I just know what it's like and how expensive it can be.* (participant 35)

Others took part because of a professional or personal interest in health, healthcare services or research, including a hospital chaplain.

> *Well I've done research myself as a nurse and trying to get study participants can be difficult so I mean it wasn't going to be, well from what read at the first instance didn't seem like it was a, going to be difficult or traumatic to do it so it was just easy, if we don't do it we don't know how to progress … so it was just a yes for me really from the start.* (participant 52)

> *No it was the first time I'd ever been asked to do a study. And because I do my own little bits of research, I did a postgraduate about – well when I was off with*

> *cancer a few years back, in travel medicine, and did a big research project on that in breast cancer and travel insurance. And I just thought, oh, it would be interesting to be part of the study. I hoped I'd be picked up with the breast cancer into a study, but I never was. Yeah so I just thought it would be interesting to do it.* (participant 882)

> *Um I've actually sat on the research ethics committee for quite a long time....Um what's now – I – I came off in October of last year. And I sat on the UHB one and the Southmead one....So it was a kind of, you know, having seen these projects sort of, you know, from the other end, I thought, oh it would be quite interesting to actually be in one for a change*. (participant 475)

Amongst the community controls, several mentioned other reasons such as having the time, perceiving the study as worthwhile, for their own enjoyment and as "my little way of helping".

Permission to access records

Four of those recruited did not give permission to access their GP records, but continued to submit participant questionnaires. Without access to GP records, we were unable to find controls to match and so these participants were excluded from analysis in the study. To learn more about their decision, we interviewed three of the four. One was not aware that he had missed out ticking the box giving permission to access his records. The other two purposely refused permission, one because of concerns about the information contained in the record about her mental health status and the other because of general concerns about protecting access to her data from strangers.

Questionnaire format

Although the questionnaires at all five time points were administered by post, we asked participants which they preferred – postal or electronic format. Equal numbers opted for each format type. One person who preferred postal questionnaires said she liked to look back to what she had written earlier and this would be harder to do with electronic questionnaires. This same person said if electronic questionnaires were used, the administration would have to be "smooth".

> *When I'm on my laptop is likely that I'm working, so I went to fill out something the other day and got so angry that it was a clunky site and I couldn't got back. I can't remember, but it was something to do with charity giving. It was something where I was predisposed to want to help them, and I ended up in a temper and just aborted. So it's got to be smooth and you've got to be able to double check what you're doing.* (participant 55)

Another mentioned that she had had difficulties in the past with forgetting her password for electronic submission and a third suggested that we ask for preferences at the recruitment stage.

Four participants commented on the layout of the questionnaire. One said that the tables for the SF-36 should not go across two pages. The other, who found the wellbeing questionnaire upsetting, suggested that we put the resource questionnaire first as it had more “technical” information and then the wellbeing questionnaire last. A third said that she liked the tick box and space format with the occasional box for ‘reason for use’ while another person said she did not like tick boxes.

Questionnaire frequency and administration

The vast majority of participants were happy with receiving and completing questionnaires every three months over five time points. One thought that six monthly returns would be fine, because of few changes in his condition while two thought every six months would be too long. Another suggested four months.

As is often the case with studies of this nature, several participants mentioned not receiving questionnaires, including one who received an opened, empty envelope. On at least one occasion, we did not receive a completed questionnaire, so the participant filled in and returned a duplicate. Early on in the study, we had a system of re-sending questionnaires if we did not receive a reply within two weeks. This tended to confuse participants and the later system of telephoning or e-mailing to remind them that a questionnaire had been sent worked better.

Questionnaire completion

Several participants commented that the questionnaires were easy to complete and did not take very long (e.g. 10-15 minutes). Several non-native English speakers took part and the two that commented found the questionnaires straightforward. One person thought that the first questionnaire could be completed by the participant with the researcher on hand to build longer term commitment to the study.

> *At the beginning it might be good to establish something. Because it takes an effort for somebody to actually say, “Right, I’ve got to put this time aside and do this.” Whereas if they’ve started off and they’ve made that sort of er commitment by personally speaking to somebody, you know, it’s easier – it’s not as easy to sort of put aside as it is a piece of paper.* (participant 891)

Some people filled in the questionnaire as soon as it arrived; others waited. Two participants mentioned questionnaires going missing in their household, one because her husband would ‘get to the post first’ and it might take days or weeks before she realised a questionnaire had arrived. They commented that they would have welcomed e-mails to remind them to fill in the questionnaires.

Most people would fill in the questionnaires in one sitting, although one very ill participant would tackle different sections over several occasions over a week. One person commented that she might partially fill in a questionnaire and then get to a resource question that required further information, leave it and then forget to complete and send. One commented that the questionnaires made her think about her condition, which some welcomed and some did not.

> *Yes it’s actually quite penetrating because it makes you think more about your own physical and mental health where normally I sweep things under the carpet a bit*

> *you know and you had to really think oh yes that is a point of view you know, I should sort of note things down more, yes it was interesting. It's not the sort of thing I would normally get involved in.* (participant 21)

> *Yeah, I did find it a little bit tricky to be honest because it maybe have been my attitude to the whole thing but sometimes I found that if I was feeling at all down it sort of underlined that, do you know what I mean?* (participant 35)

> *I thought it was – it was OK because what helped was having those kind of questions again and again made you realise that actually, you know, you've progressed quite a lot more. Because sometimes we don't realise it (possibly) um how quickly we have progressed until you look back and you think, "Oh actually, you know," so no I think that was quite good, because it makes you stop and think, "What actual tasks can I do and what do I struggle with?"* (participant 891)

Those with multiple conditions sometimes found questionnaire completion more challenging as they were not sure if they were supposed to respond for the particular matching condition or for their overall health.

> *Yeah because I was – that was to do with the sciatica I'd been having. And I thought, "Should I be answering it on that basis or to do with the anxiety?" That's – that's kind of just brought into my mind how I was looking at that actually. And then as I was looking at the questions I thought, "Well that must, you know, that must be to do with that." And then when I come across these, to do with physical things, I can remember thinking, "Oh hold on, which should I be answering that on?" Because physically, like doing physical um lifting and things, anxiety didn't stop that, it didn't come into that. Whereas obviously sciatica did....And I think that made me a little bit unsure.... Because it was never given a definite - you know, it was 'your condition', not 'your um anxiety condition'.* (participant 10)

Another woman commented that she developed a new symptom while in the study and was not sure whether to respond with this taken into account. Others mentioned that much of the questionnaire was not relevant to their condition and so they were not sure whether to skip the non-relevant questions and only respond only to the pertinent questions or to complete the whole questionnaire.

Several people added handwritten messages to explain their answers, to query the information required (e.g. 'do you mean 'pain' or 'discomfort'?) or to comment on the progress of their treatment. These participants would have welcomed a box with 'anything else?'

One participant reflected that some people, like her might complete the questionnaire quickly without much thought, while others would take more time to think about their responses.

> *When I do questionnaires I tend to, you know, read the question and, you know, go for it. I know, from my husband, he has to think about these things. And before we got married we went to one of these sort of marriage preparation classes, and the*

> *thing that was really startling was that we got questionnaires, and I filled mine in, in about five minutes flat, and he got about half way through during the evening. He has to really think about these things. I mean I just go with the flow and fill them in.* (participant 475)

One BHH participant disclosed that she embellished her responses to reflect positively on homeopathy.

> *And that's um – and – and sort of finding – you know, choosing a point on that continuum is quite hard. But I think – and also I have to be really honest and say that I think my – I think, I don't know if this is true, but I think it's possible that my answers were influenced by my wish to (laughs)....It sounds terrible but um....you know, to want there to be a positive outcome with homeopathy.* (participant 064)

Another person stated that she did not want to give information about her family or family income for privacy reasons, however in checking her questionnaires that information had been completed except for salary.

Everyone asked said that they followed the timeline instructions on the questionnaires, for example they included all resources for the past three months not since the last questionnaire.

Incentives

Participants received either a £5 voucher whenever a questionnaire was returned or a £5 donation to a charity of their choice for each returned questionnaire. The majority of participants also received either a teabag with a handwritten and signed post-it note saying 'Have a cup of tea on us while you complete the questionnaire' or an After Eight mint chocolate with either the first or second follow up questionnaire.

Many participants remembered receiving the vouchers. Despite the information sheet clearly mentioning the vouchers, a couple said the receipt of the vouchers was "unexpected". All but two participants said that the vouchers did not influence their decision on accepting the study invitation or returning questionnaires. Instead, some saw the vouchers as a "nice bonus" to spend either on themselves or family members.

> *It was a nice bonus for the girls, because I gave it to the girls. Um but no, I er – like I said, I really value homeopathy, so um it's important to me that, you know, we do what we can to support, um and make sure it does remain established.* (Participant 891)

Others saw it as a 'thank you' or gesture of appreciation.

> *I probably would have done it anyway. It was just nice that you had that acknowledgement that, you know, "Thank you, you're doing something that's useful." But I would have done it anyway I think, yeah.* (participant 902)

Another said the vouchers bonded her more closely to the study team.

> *RESPONDENT: I felt – I felt a sort of um – a bit of a bond with er (laughs)*

> *INTERVIEWER: Ah with the people with the study, for example?*
>
> *RESPONDENT: Yeah because you did seem to appreciate my taking part, so I think that was important.* (participant 064)

Two respondents, one of whom had been on Incapacity Benefit for a long time, viewed the receipt of the vouchers as payment for participation.

> *I hope I'd have kept going anyway but certainly I would have felt guiltier if I hadn't done them, so I think it did make a difference I have to say, I know that sounds awful but you know it's like you're being paid for something and if you don't do it then...* (participant 35)

Most people had no problem with the vouchers, but a couple of participants who lived in more rural places found it harder to spend them as no local branches of those high street shops were available.

Seven people of the 45 in the study opted for charity donation to charities including a food bank, Oxfam and Cancer Research. Setting up these charitable donations through the University financial system was complicated and eventually accomplished through the 'cheque request' system.

Although the voucher or charitable donation system was universally popular, there were more mixed views on the teabags and chocolates. No one thought the teabags or chocolates influenced their decision to respond. However, some people responded positively with "smiles" or "giggles".

> *That's a really nice touch, very off your low cost intervention but actually it just means that you're sort of considering the person that's filling it in.* (participant *52)*

Others had a more negative response saying that they thought it "was rather a weird thing to do" or a gimmick that might put them off. One person did not drink black tea and was allergic to chocolate and so gave her After Eight mint to the dog.

Questionnaire relevance and sensitivity for wellbeing and quality of life

The questionnaire pack was 6 pages double sided and consisted of the Warwick Edinburgh Wellbeing questionnaire, SF-36 and an adapted Client Service Resource Inventory in that order. Some of those recruited early to the study also received a questionnaire specific to their condition e.g. 'Hot flush frequency and severity scale' but this was dropped as too few people with each condition were entering the study to draw any meaningful conclusions.

However, this did mean that with only the generic tools of wellbeing and quality of life, many participants were not clear how the questionnaires were relevant or would capture any changes in their health related to their treatment. For example, one participant said that the wellbeing and SF-36 questionnaires would be more appropriate for those with severe depression and 'considerable disability' respectively, not for someone like her with hot flushes. Another commented

> *I think I would imagine that it probably seems like either a very small shift or about the same, but that is perhaps because I'm sort of estimating overall what I'm feeling. And I guess because, in terms of the hot flushes, there's no questions in there that directly relate to that.* (participant 902)

Another woman with tamoxifen induced hot flushes agreed about the lack of relevance.

> *That was what I found not relevant yeah. Because I felt that my quality – I mean I run four miles a day, it's what I do. It's not affecting my life, you know, the problem, I just get on with it.* (participant 882)

Another participant, who also said that the questionnaires were not relevant for her conditions of high blood pressure, palpitations and hot flushes, was asked if a 'patient reported outcome measure' questionnaire such as MYMOP would capture these changes more appropriately, but her response was that it would not as her conditions were intermittent. The intermittent nature of their condition affected how others completed the questionnaires as well, as they attempted to bracket or even out the changeability.

> *But then when you think about a year ago, you know, you use these, it didn't have the same type of impact, if you know what I mean. Because you would go a year back and oh I'll – and then you have to be honest with yourself and you think, "Actually this is the time of the month where I feel pretty (laughs) horrible anyway." So you try to let that not affect.* (participant 939)

> *So I had to stop and think, "Now hold on, now actually the other day I wasn't – that wasn't good for that." You know, I might have not ticked it quite up so high. And then that – but the day I was doing it, I was good....So then it was judging, you know, which to put.... For that, you know, that two – was it two week? – yeah two week, over the two week period....So then it was – I had to sort of think about things a little bit, "Now hold on, did anything happen? How was I?" and sort of, you know, give a bit of thought to it. Because it could have changed within those two weeks a little, on and off a little bit. If anything had happened that bothered me, then that would have changed that – those few days, you know.* (participant 10)

> *Well I sort of felt that I was averaging out all the time. Because you sort of think, the last two weeks, and sometimes it had been very up and down, and you think, "Well what is my answer? I'm not going to say that's all the time, because it's not. It's not – none of the" – do you know what I mean?* (participant 902)

Several mentioned that their wellbeing and quality of life were less affected by their condition and more affected by life events.

> *If the police have been visiting or something, I'm stressed. Because I've never been used to it. We've never been used to it. And it does stress you. It's very different to what you're used to, and quite frightening. And yes that does alter how I'm feeling. So I would say that that would be the reason. Or my mother, who is continually ill with big things, cancer, triple heart bypass, all the time, on and on, you know, always. So there's both those things that really do affect my life. Oh and my*

> *husband being out of work for two years as well. So all that has been in the last few years.* (participant 882)

However, although several participants queried the relevance and appropriateness of the wellbeing and quality of life tools in capturing changes in their condition, there was universal acknowledgement that these questionnaires did accurately reflect the 'ups and downs' that they had experienced over the preceding year. Moreover at least one participant did notice that her responses to the SF36 changed as a result of homeopathic treatment.

> *I mean when I was having them all through the night and all through the day, then obviously that did impact on my quality of life. But by the time I started taking the medications, then that really was controlling it. So really it wasn't making that much difference to my quality of life.* (participant 975)

Nonetheless, despite these doubts about the usefulness or relevance of the SF36 and wellbeing tools, the quantitative analysis of the data collected from both tools suggested that changes were captured. Furthermore, the changes captured were validated across the tools.

Resource questionnaire completion

The resource questionnaire appeared to require more effort from participants.

> *...bit of a bore having to kind of um, you know, check what – how much everything I – because I do, as you noticed, I do use quite a lot of things.... So I did have to, you know, make the effort to find out how much those things cost, which was a bit tiresome. But apart from that, and I expect I probably forgot one or two things, but um no that was OK.* (participant 064)

Some mentioned that they filled in the questions on visits to the GP surgery or hospital from memory, which was unproblematic for low resource users, while others consulted their diaries or a calendar. More consistently, participants tended to check prescription bottles to complete the medications section.

Participants had more difficulty completing the over the counter medications section. Preparations bought in supermarkets often did not have prices on them so participants would sometimes guess, although one went online to chase up current prices. Another difficulty was pricing offers such as three for two. However overall, the quantitative results suggest that capturing these costs is useful and important.

For both prescription and over the counter medications, there was the discrepancy between what the participants were taking versus what they were buying, which had an effect on cost calculations. For example, if someone bought a six month supply of a product and listed it on two questionnaires, they would only have had the expense once but we would have costed it in twice.

Several people mentioned that they did not think the resource questionnaire was relevant as they did not use much healthcare.

What was not recorded

Most people thought their recording of healthcare costs was complete. In several interviews when asked about what they might have left out inadvertently, participants mentioned community funded group counselling, chiropodist, grief counsellor and over the counter painkillers like paracetemol and ibuprofen which they thought they had not recorded, although all had.

For those resources identified during interview that should have been recorded, at least two participants mentioned missed regular over the counter preparations on one questionnaire (ie iron supplements, echinacea). One neglected to record an x-ray. One missed a consultation with a nutritionist. One participant recorded an activity (chi gung) and another a private treatment (acupuncture) without the complete, accurate costs. Two others had private biomedical treatments e.g. private consultation with a cardiologist and a private x-ray, but did not make it clear on their questionnaires the private nature of the funding.

Activities and costs that were left out because the content of the form did not encourage their recording tended to fall into four areas: 1) exercise, 2) no cost health or wellbeing related activities 3) private healthcare usage or 4) NHS community clinics. For example, one participant mentioned that she went to a weekly yoga class for her health at £7 a session, but did not include this. Another went regularly to a gym and another went running. Several participants mentioned walking. No cost health related activities included free reiki sessions and spiritual activities such as attending Quaker meeting, sessions with a spiritual director or daily meditation. One community participant had private medical homeopathic treatment, which she did not record at all. During interview, another participant clarified that she had had three musculo-skeletal treatments at a community clinic and the letter of discharge in the medical records did not give details on total number of treatments.

To capture no cost and more spiritual and exercise health related activities, several respondents thought we should include the question: ‘is there anything else you do physically, emotionally, mentally or spiritually for your health or wellbeing?’ When this question was put to successive participants, we were informed that they were more likely to give information about exercise, diet and spiritual practices.

The recording of personal costs also challenged some people as they were not sure what to include e.g. parking tickets, mileage. We found that a minority of people recorded large personal costs, such as lost earnings and extra childcare costs, which increased the variability of the study results. One participant mentioned that she paid someone to do the ironing, which she did not include and her husband does the vacuuming. To capture these, she suggested that the instructions ask for information on ‘any help, paid or unpaid’.

Two participants thought we needed to ask more about motivation for Bristol Homeopathic Hospital use.

> *The question isn’t asked, you know, ‘why did you ask for, or why were you brought into the homeopathic hospital in the first place?’ Because I guess that would have*

> *been fairly revealing....Um and, you know, in any kind of um look at the homeopathic hospital, I mean I guess I would want people to actually look at um, you know, the reasons why people use the homeopathic, and whether it does actually keep them out of conventional hospitals.* (participant 475)

Attributes for a discrete choice model

As part of the exploration of different economic methods to evaluate homeopathic packages of care offered by the Bristol Homeopathic Hospital, we took the first steps in building a discrete choice model. These values were classified around values concerning the service and values relating to the treatment.

Table 8 What Bristol Homeopathic Hospital participants valued most about the service

What valued from the service	**Number of participants who mentioned**	**Participants who mentioned**
Extended length of consultation	4	113, 975, 939, 902
Convenient location of satellite clinic or BHH premises	3 + 1	882, 987, 073 + 902
Free	2	987, 974
Information leaflet	1	113
Welcoming, less businesslike atmosphere	1	891
No computer	1	073
Access to a medical doctor who pays attention	1	902
Option for a condition that can't be conventionally treated	1	985
Thursday afternoon phone in sessions between appointments	1	902

Table 9 What Bristol Homeopathic Hospital participants valued least about the service

What found less helpful	**Number who mentioned**	**Participants who mentioned**
Long gaps between appointments	5	987, 113, 985, 939, 902
Hard to get hold of homeopath between appointments	3	987, 985, 939
Hard to get an appointment	2	974, 939
Booking system (changing or swapping an appointment, booking appointments for 2 or more family members on the same date)	1	891
Letter for follow up appointment lost in the post	1	985
Long wait for initial appointment	1	902
Taking off work to attend appointment	1	882
Travelling to get to BHH clinic	2	975, 158
Parking at BHH clinic	2	939, 919
Paying for parking	1	939
Consultation too short	3	113, 064, 891
GP doesn’t know anything about homeopathy	1	985
No refresher information leaflet for longterm attenders	1	475

Table 10 What Bristol Homeopathic Hospital participants valued most about the treatment

What valued from treatment	Number who mentioned	Participants who mentioned
Positive impact on health	5	974, 073, 975, 158, 891
Type of questions homeopath asked	4	97, 939, 902, 475
Personalised approach (ie not a number)	2	073, 902
Careful identification of treatment/ remedy	2	073, 919
Broader scope of interest than presenting symptom	2	902, 475
Listening skills of homeopath	2	974, 939
Learning about yourself	2	974, 975
Practitioner that ‘thinks outside the box’	2	475, 891
Consideration of relationship between symptoms	1	975
Remedy prescribed for ‘all different things that I have’	1	113
Practitioner ‘got to the bottom of things’		919
Low side effects	1	113
Opportunity to express your feelings	1	919
Practitioner creates safe space	1	113
Reduction in use of GP consultations and prescriptions	1	974
Trusted practitioner	1	064
Experienced practitioner		064

Table 11 What Bristol Homeopathic Hospital participants valued least about the treatment

What found less helpful	Number of participants who mentioned	Participants who mentioned
Lack of any effect	1	882
Lack of an immediate effect	1	975
Couldn’t answer homeopaths questions	1	064
Bad reaction to remedies	1	064

The larger study would need to develop these attributes further to determine which values were of the most importance.

Key learning points

- To recruit BHH participants for a future study, we could ask the BHH secretaries to hand out invitations, participant information sheets, consent forms (and possibly health status and quality of life questionnaires?) to new patients at the BHH before their first appointments. A researcher would then be on hand on the premises at BHH at the first appointment to carry out written consent, collect completed questionnaires and administer any incomplete questionnaires. Hopefully this would enhance the quality of responses received and build longer term commitment to the study.

- Hopefully this would enhance the quality of responses received and build longer term commitment to the study but the disadvantage is that baseline would take place after the first appointment.

- The consent form should include an option for questionnaire format preference - electronic or postal. Postal questionnaires should be checked to make sure that the layout has not been disturbed in printing. Administrating questionnaires every 3-4 months is about the right frequency. All returned questionnaires should be read by the researcher when they come in to pick up on any problems or answer participants' queries.

- The vouchers were perceived as messages of thanks, appreciation and payment. They were popular and should be incorporated into the design of any future study. The teabag and chocolates might not be as useful.

- We need greater clarity on what resource use we would like recorded. The issue is that the resource questionnaire gives information not only about costs and but also about treatments. So for example, it would be useful to capture 'free' complementary therapy consultations like reiki, as that gives an indication of complementary therapy use, but knowledge of other free activities like walking would be less useful.

- The resource questionnaire, quality of life questionnaire or 'a little about you' could go first as they may be easier to answer. A box for 'is there anything else you want to add?' should be included for those who like to explain their answers or add extra information. The resource questionnaire needs to be modified to capture day surgery, private healthcare resource use, private medical, non-medical and over the counter homeopathy, private and NHS counselling. Given that participants reported checking their medication bottles to complete the medication, we could ask for more specific information on strength and form to more accurately price prescriptions. To capture no cost interventions and spiritual and exercise health related activities, include the question 'is there anything else you do physically, emotionally, mentally or spiritually for your health or wellbeing?

- Although participants queried the usefulness of SF36 and the wellbeing tool, quantitative analysis found that the data collected did capture changes. Moreover, the use of both tools with similar results validated those findings. Therefore, SF36 and the wellbeing tool appear to be appropriate for the Bristol Homeopathic Hospital population. The resource questionnaire is fairly comprehensive in encouraging respondents to record a wide range of resource usage and with modifications would also be useful in a larger study. Capturing health outcomes in a tool such as MYMOP could be useful.

- The attributes of top value to Bristol Homeopathic Hospital participants were extended consultation length, positive impact on health and convenient location.

Part IV Comparability between cases and controls

How good is the match?

Comparison of matching criteria and healthcare usage

A key issue in designing a larger study is ensuring a 'good enough' match between case and control participants. With the prospective controlled cohort design, the assumption was that by matching for index condition, individuals with similar patterns of healthcare resource use would be recruited. This section of the report draws on medical record and interview data to test the viability of that assumption.

For the quantitative analyses, we matched 9 case participants to 17 community controls, making 17 matched pairs. For the qualitative analysis, we explored 8 of those 17 in depth. The interim report discussed difficulties in matching at control participant selection namely:

- Although the protocol listed the criteria for matching as GP practice, sex, age within 5 years, condition and frequency of consultation within 2 consultations, we found that the final criterion eliminated almost all potential matches and did not appear to be a good proxy indicator of severity of disease. So we matched on the first three criteria alone.

- In four out of 12 cases, the condition cited on the referral letter was not the condition which was used for searching, because homeopathic treatment was not for the referred symptom or because the symptom was not noted in the patient's GP medical records.

- The quality of coding varied tremendously and sometimes the case participant consistently did not appear amongst the 'hits'.

- Although the stated criteria for matching were clear, some interpretation was necessary (e.g. extending the date of first onset of hot flushes from a 6 monthly to a 12 monthly time period). When faced with an array of potential candidates, a systematic selection protocol is necessary but challenging to devise.

- Controls were more likely to be identified for conditions such as menopause or depression or from bigger practices with list sizes of 7,000 or more. Controls were less likely to be identified for more unusual conditions or from smaller practices. The combination of a small practice list size and an unusual condition made finding controls nearly impossible.

Nonetheless, despite these challenges, quantitative analyses found that the cases and controls were well matched at baseline for quality of life and wellbeing, but not for resource usage. The following table provides a breakdown in terms of matched pairs to explore the matching of condition and healthcare resource usage further.

Table 12 Comparison of case and control participants by conditions and healthcare usage

Case or control	Id number	Sex	Age	Practice	Matching symptom	Other conditions mentioned in interview or in medical records	GP consults in medical records at baseline	GP consults in medical records intervention	CAM use
case	882	F	53	Somerset market town 1	Hot flushes	Previous history of breast cancer, dyspepsia, kidney polyp	3	4	BHH homeopathy, OTC herbal, hypnotherapy
control	6	F	52			Back and shoulder pain, IBS	5	12	Acupuncture, spiritual healing, echinacea
control	10	F	54			Sciatica, anxiety	19	11	OTC homeopathy and herbal, relaxation and breathing
case	939	F	43	Somerset market town 1	Low mood	Headaches, mood swings	4	0	BHH homeopathy, acupuncture, reflexology, supplements, Hopi candle,
control	14	F	48			Arm pain, depression, migraines	9	5	Physiotherapy delivered acupuncture

Case or control	Id number	Sex	Age	Practice	Matching symptom	Other conditions mentioned in interview or in medical records	GP consults in medical records at baseline	GP consults in medical records intervention	CAM use
case	985	F	60	Somerset rural	SVT	Bigeminy, arrhythmia	2	1	BHH homeopathy, OTC herbal
control	21	F	64			Suspected hypothyroidism	5	3	OTC homeopathy, supplements echinacea
case	475	F	51	Bristol urban 1	Hot flushes	High blood pressure, breathing problems, palpitations	3	2	BHH homeopathy, Chiropractic, supplements
control	22	F	48			Thrush, conjunctivitis, herpes, URTI, neuralgia, earache, hamstring sprain	17	12	None recorded
control	23	F	54			Asthma, earache, red eye	7	3	None recorded
control	24	F	48			Depression, hypertension, epilepsy, dermatitis, arthmalgia	17	8	Data not available

Case or control	Id number	Sex	Age	Practice	Matching symptom	Other conditions mentioned in interview or in medical records	GP consults in medical records at baseline	GP consults in medical records intervention	CAM use
control	25	F	47	Bristol urban 1	Hot flushes	Calf sprain, palpitations, hypothyroidism, piles, leg pain, boils	4	6	Data not available
control	26	F	50			Sciatica	2	3	OTC herbal, OTC homeopathy
case	064	F	58	Somerset market town 2	Chronic fatigue	Back pain, IBS, thyroid, basal cell carcinoma	15	12	BHH homeopathy, supplements, ‘environmental medicine’, medical herbalism
control	35	F	49			Digestive, menopausal, thyroid, back problems, insomnia	17	10	Acupuncture, nutritionist, lightening process, ‘complex’ homeopathy, OTC herbal, flower remedies

Case or control	Id number	Sex	Age	Practice	Matching symptom	Other conditions mentioned in interview or in medical records	GP consults in medical records at baseline	GP consults in medical records intervention	CAM use
control	36	F	58	Somerset market town 2	Chronic fatigue	gastritis	17	7	Medical herbalist, vitamins & supplements, spiritual healer, massage
case	891	F	39	Gloucester urban	Low mood	Fatigue, painful feet, headaches, neck pain	6	1	BHH homeopathy, Acupuncture, cranial sacral
control	39	F	42			Back pain, chest infection, vaginal bleeding, ear wax	N/A	6	Chiropractic
control	42	F	38			Tired, depression, joint pain, boils, UTI	7	7	Vitamins & supplements
case	055	M	44	Bristol urban 2	Knee pain	Dermatitis, joint pain	6	3	Data not available
control	47	M	45			asthma	5	8	Vitamins & supplements
control	49	M	46			Cellulitis, gout, bursitis, hypertension	12	3	Osteopathy

Case or control	Id number	Sex	Age	Practice	Matching symptom	Other conditions mentioned in interview or in medical records	GP consults in medical records at baseline	GP consults in medical records intervention	CAM use
case	902	F	44	Bristol urban 2	Hot flushes	Breast cancer, cellulitis, lymphedema, hearing problems, carpal tunnel	22	17	BHH homeopathy, chi gung, shiatsu, supplements
control	51	F	44			Nothing else	3	3	None recorded
control	52	F	41			Fertility, neuralgia, migraines	3	3	OTC homeopathy, OTC herbal
case	975	F	52	South Gloucester-shire rural	Hot flushes	Breathlessness, tennis elbow	5	5	BHH homeopathy, OTC herbal, massage
control	55	F	54			Depression, dyspepsia, shoulder and knee pain	0	1	Medical homeopathy, yoga, meditation
control	56	F	47				1	1	supplement

As anticipated, this table suggests that participants are well matched for GP practice, age and sex. Matching for symptom seems more variable. Although some pairs (e.g. 064 and 35) appear well matched both for presenting symptom and other conditions and consequent resource use, others appeared to have quite distinct health conditions with varying levels of severity and disparate levels of resource use, for example 902 with hot flushes and recent breast cancer and 52 with hot flushes and neuralgia.

If we define ‘low’ NHS resource users as those who visited the GP five times or less (five is approximately the national average), and ‘medium’ resource users as those who visited their GP 6-10 times and ‘high’ resource users as those who consulted 10 times or more, of the 27 participants who have baseline data, 8 were high users, 7 were medium and 11 were low. Eleven participants changed their NHS resource user category from baseline to intervention year, of which 3 increased their visits to the GP and 8 decreased. In terms of CAM use, of the 25 participants for whom we have data all but three of the case and control participants consumed a variety of complementary therapies consisting of over the counter and/or face to face consultations.

The results from this table challenge our supposition that individuals with the same condition will consume the same levels of healthcare resource. For example, 975 and 55 were well matched for ‘natural’ menopausal hot flushes, yet 975 suffered from the additional, relatively minor complaints of tennis elbow and breathlessness while 55 had more severe complaints of long term depression with joint pain and dyspepsia. This would suggest that 55 would consult more, given the more serious nature of her condition. But in fact, 55 was a very low user who did not consult her GP once during the baseline year while 975, with more minor complaints, visited her GP practice 8 times at baseline. Yet both women sought out the same type of non-NHS healthcare for their hot flushes (medical homeopathy). So although these two women were well matched for index condition and the type of healthcare selected, arguably they were not well matched for overall health status or quantity of resource usage.

Overall, this table suggests that the relationship between condition and resource use is much more complicated than our original supposition. Matching on index condition alone does not appear sufficient to ensure adequate matching of resource usage. Co-morbidities and other factors appear to play a part. This is explored further in the next section.

Ways in which participants make healthcare choices

To understand more about the rationale behind participants’ choices and their relationship to healthcare consumption, we carried out qualitative interviews. This was important, given that reasons for and attitudes towards healthcare consumption might strongly influence the healthcare resource behaviour observed in medical records and participant questionnaires. Thus in interviews, we asked seven case and eight community control participants:

- What healthcare resources they consume.
- Why they make the choices that they do.

- How they combine different types of healthcare resources (e.g. self-help, NHS, complementary therapies).
- The role of the Bristol Homeopathic Hospital.

Fuller synopses from participants are available in Appendix F, however here we present abbreviated accounts. These are reported in matched pairs, to help illustrate the complexity of matching.

Comparison of participants' relationship to healthcare consumption

Pair A case 882 & control 6 and Pair B case 882 & control 10 Index symptom = hot flushes

With low recorded NHS healthcare resource use at baseline, despite her history of breast cancer, case participant **882** is a nurse specialist who has private healthcare insurance (BUPA) because it gives her easy, fast access to her preferred provider of her private breast surgeon. Once she finds a practitioner who delivers results and whom she can respect, she becomes a 'loyal customer'. She has little faith in her GP who misdiagnosed a kidney polyp and did not successfully treat her cellulitis. She uses over the counter remedies for minor conditions. In addition to homeopathy at Bristol Homeopathic Hospital, she has had hypnotherapy, but her first 'port of call' would be her private breast surgeon whom she has visited for over 20 years. Her GP suggested treatment at the Bristol Homeopathic Hospital for tamoxifen induced hot flushes, which she discontinued, as she did not notice an effect. 882 makes her choices on the basis of results and perceived competency.

With high recorded NHS resource use at baseline, the first matched pair for 882 is control participant **6,** who is a former nurse now retired from ill health. She has chronic pain in her back and shoulder and IBS. Although matched for hot flushes, these were not mentioned once in the interview. She visits her GP frequently, partly because she says her family may be tired of listening to her complaints and she has limited other support. Although she likes her usual GP she does not feel that he 'takes her seriously' enough and she has to 'persist' in 'going back' with frequent consultations for the same condition. She seems hesitant about making direct requests (e.g. she wants physiotherapy for her back but in 11 years has only broached this with the GP once). She takes supplements as preventative medication. She has had NHS physiotherapy delivered acupuncture and self-funded grief counselling. On several occasions, she mentions that cost prevents her from taking a particular course of action, and she is on Incapacity Benefit. 6 appears to consume substantial amounts of NHS resources because she has chronic, unresolved health problems resulting in needs not met by her GP, her family or her informal support systems.

The second matched pair for case participant 882 is control participant **10** who is a part-time school lunch supervisor with high levels of anxiety and sciatica. As a high NHS resource user, she visits the GP most months for multiple reasons including: following doctor's orders, seeking advice (and possibly permission?) and monitoring for undetected conditions or to confirm health stability. A key word in this interview is 'check'; she talks about various investigations 'checking' her health status and how she consults the GP to 'check' a particular course of action. She has a particularly good relationship with one GP, whom she credits with finding the right combination of treatments for her panic attacks and anxiety (diazepam, counselling, Tai Chi and working in a charity shop). She appears to be more comfortable with professional advice from the GP, the chemist or even a counter assistant at Holland and Barrett rather than choosing medications herself. She is not adverse to complementary therapies, but appears to prefer conventional medicine. Had her GP suggested a referral to Bristol Homeopathic Hospital, she would have considered it because the recommendation came from her doctor. 10 consumes a lot of NHS resources because she is worried and trusts the experts to help.

Thus in comparing these two pairs, all of whom suffered from hot flushes, case participant 882 appears to be highly self-directive looking for competency and a partnership with her preferred healthcare provider, who happens to be privately funded. She consumes much less healthcare, usually in an acute situation or in annual reviews for her chronic breast complaints. In contrast, control participants 6 and 10, neither of whom have had breast cancer like 882, consume substantially more healthcare because of chronic ill health and unmet need (6) or because of anxieties about hitherto undetected conditions (10). In all three cases, the motivations for seeking out healthcare appear significantly different.

Pair C Case 939 & control 14 Index symptom = low mood

A medium user of NHS healthcare resources for her headaches and mood swings, case participant **939** is an alchemist who believes in combining treatments to maximise their effect. A practising midwife and long time user of homeopathy, she accesses biomedical services and investigations to check the seriousness of a condition and homeopathy and acupuncture to manage her conditions. Although taking some powerful biomedical medications (diclofenac, zomig), she attributes improvements to homeopathy. In deciding which treatments to use, she considers cost, safety, side effects and accessibility of appointments and clinic premises. She is willing to pay for private treatment, but only if she discerns the benefit that is worth the expense. She has a good relationship with her GP and her GP is informed of and willing to discuss alternative treatments. She does not expect more from her GP and rarely consults. 939 experiments with her healthcare choices and the wide field of possibilities includes biomedical and complementary options.

A high user of NHS healthcare, control participant **14** suffers from depression, migraines and neuralgia. She has a difficult personal life raising three children on her own. Although she has paid for private acupuncture and private counselling, both during the intervention year of the study, her healthcare choices are now limited to what is free. So currently her treatment options are prescription medications and cheap over the counter preparations such as paracetamol, ibuprofen and a migraine remedy. If she had been offered NHS homeopathy for either her neuralgia or her depression, she would have taken it, despite the travelling, but her GP did not suggest this. Her expectations of improving her health status are low, so she tries to diminish the intensity of the symptoms. In the absence of other alternatives, she regularly consults her GP, primarily for her depression and less so for her pain as she seems resigned that little can help. 14 makes her choices from a limited, proscribed NHS menu, as there is no cost.

In comparing case participant 939 and control participant14, both have headaches and take powerful pain medication in addition to suffering mood disturbances, so superficially they appear to be well matched. But their approach to healthcare is very different. Whereas 939 mixes and matches a variety of healthcare options to potentise their effect, including private healthcare, 14 is limited to what is immediately and freely available – the GP and NHS medications. Fundamentally, 939 is a great believer in complementary therapies, exercises 'choice' and consumerist tendencies while 14 does not and cannot in her present circumstances.

Pair D Case 985 & Control 21 Index condition = SVT

A retired GP, case participant **985** is a low user of NHS resources. She has bigeminy and arrhythmia and asked for a referral to the Bristol Homeopathic Hospital because nothing else had worked. Given her background and training, unsurprisingly her orientation is towards biomedicine, although she has had some training in homeopathic prescribing. Her GP would be her first port of call, but she only seeks medical attention when she does not know what is happening or when she knows she needs treatment. Otherwise, her tendency is 'to let nature take its course'. Like 14, case participant 985 perceives a limited menu, not through lack of funds, but because she believes her condition is largely untreatable. So her decisions are made on the basis of options that might help, but by and large few healthcare choices are made, as she is resigned to living with her condition.

A medium NHS resource user, community control **21** is also retired and has 'a nice, comfortable life'. She suffers from heart palpitations from a genetic disorder and borderline hypothyroidism. She and her husband have a joint approach to healthcare, relying mainly on bulk over the counter herbal remedies for minor conditions and prevention. She consults a GP when she is unfamiliar with the condition, when her chronic condition deteriorates, with new, more serious symptoms and when she experiences side effects from her medication. She likes complementary medications, but does not seek practitioner based care, partly because she sees it as expensive. She would have followed up referral to the Bristol Homeopathic Hospital, if her GP had suggested it, because she is curious about complementary therapies, not because she has unmet health needs. Rather her motivation for seeking healthcare seems to be instigated by changes in physical health, based largely on finding relief for symptoms that interfere with her daily life.

In comparing case participant 985 to control participant 21, not only do they have similar symptoms, but they also have similar approaches to seeking out healthcare. Although 21 relies more on over the counter supplements for prevention, both women tend to self-manage and only consult if alarmed by new symptoms. However, despite these similarities, the quantity of NHS healthcare resource usage is quite different.

Pair E case 475 & control 26 Index condition = hot flushes

A low NHS resource user, case participant **475** suffers from high blood pressure, breathlessness, palpitations and hot flushes. She believes that she reacts badly to biomedical preparations and as a result, she has attended Bristol Homeopathic Hospital intermittently for six years to reduce her dependency on conventional drugs. She is happy with biomedical care for diagnosis but prefers homeopathic treatment and credits attendance at Bristol Homeopathic Hospital with her minimal NHS resource use. She takes several over the counter preparations (e.g. Vitamin E, starflower oil, calcium) and sees a chiropractor for an old whiplash injury every six weeks. Nonetheless, her GP would be her first port of call for a new symptom, unless it was her back when she would call on her chiropractor. Nonetheless, she does not feel that conventional medications are an option, so her only recourse is homeopathic treatment, whether at the Bristol Homeopathic Hospital or privately, and 'natural' over the counter preparations. 475 makes her choices on the basis of avoidance of pharmaceutical medications.

Like her matched case participant, control participant **26** is a low user of NHS resources because: she views her ailments as minor (menopause and sciatica); she believes that GP treatment is largely limited to prescription medication; she finds it difficult to get an appointment with her GP and she does not want to wait for treatment. When a condition arises, except for her ears which she seeks help for quickly as she is clinically deaf, she usually waits for the condition to clear up on its own or goes to the chemist for something over the counter. If that does not work, she will then seek GP services or in the case of sciatica she will pay for private treatment from a physiotherapist who has previously offered relief. Her inclination is towards biomedicine, although she sees complementary therapies as 'having a place', for example the over the counter herbal remedies were appropriate for night waking and sweats because menopause does not need 'curing'. Due to the ineffectiveness of these over the counter remedies, she sought HRT because of symptom severity and a change in her circumstances. She takes over the counter preventative supplements such as Omega 3 and evening primrose oil. Despite knowing nothing about homeopathy, she would have taken up a referral to Bristol Homeopathic Hospital, if it had been suggested by her GP, as she wants to avoid medication. She says her GPs are 'brilliant' but she does not seek a close relationship. 26 makes her choices out of expediency and avoidance of medication.

In comparing case participant 475 and control participant 26, both have the index condition of 'natural' hot flushes and are low resource users. Although both stated that they want to avoid pharmaceuticals, this motivation has a major influence on the choices that 475 makes with her preference for homeopathy while 26 now is on longterm HRT, possibly because 26 does not perceive complementary therapies are particularly effective.

Pair F Case 064 and control 35   Index symptom = chronic fatigue

A high NHS resource user, case participant **064** has chronic fatigue, back problems, IBS, thyroid conditions and basal cell carcinoma. She is anxious about her health and consumes a lot of NHS and private healthcare, despite being on a low income of less than £10,000 annually. She worries about hidden, not easily detected causes of ill health such as viruses and environmental contaminants. She wants long consultations so she has enough time to disclose and 'work out' possible causes for her ill health in collaboration with her practitioner. She wants someone who accurately diagnoses and treats competently. So for example, she appears disappointed with her GP and her biomedically trained environmental doctor as they did not initiate investigations into thyroid imbalances when she complained of tiredness. In contrast, she highly rates her herbalist who suggested that she take thyroxine despite the borderline test result and she felt better. She does a lot of her own research online and from books, buys over the counter products and is happy to self-treat. Her first response to a new condition would be ‘panic’ followed by looking for information. Then she would consult her herbalist, the GP or self-treat, depending on the condition. She thinks her GPs are very ‘warm’ and ‘open minded’ but despite 21 GP practice consultations at baseline, she says they would only be her first port of call for infections or in an emergency. Although she ‘passionately’ believes in homeopathy and initiated the referral to Bristol Homeopathic Hospital, she was not particularly satisfied with her experience as the follow up consultations were too short and she was not sure that the remedies made a difference. She also does not follow up on every referral, as she received a referral to the chronic fatigue clinic which she did not take up. This is a woman who views her health as puzzle, so she would prefer to make choices with competent practitioners who have the time and expertise to work out the next piece of the puzzle. However given her limited income and her anxiety, in practice she often turns to her GP, despite the short consultations and perceived lack of effectiveness.

Her matched control **35** is also a high NHS resource user. Living on Incapacity Benefit, 35 has chronic fatigue, disgestive problems, menopausal symptoms, thyroid irregularities, back pain and insomnia. Her ill health was sufficiently severe that the interview took place over three dates, because of fatigue. She uses copious amounts of complementary and NHS healthcare resources and will try anything recommended from healthcare practitioners, friends, over the counter assistants and even leaflets. Having experienced many treatments e.g. acupuncture, herbal medicine both privately and in the NHS, she appreciates the extra time from private consultations but the expense is a consideration. She says she would self-treat as a first response to a new condition and then see her GP. She might have accepted a referral to the Bristol Homeopathic Hospital. She had ‘complex’ homeopathy previously from a private practitioner who was a former GP, but she is not sure whether ‘normal bog standard’ homeopathy is effective. 36 makes her choices out of desperation to find something that will help.

In comparing case participant 064 and control participant 35, there were many similarities in relation to index condition, co-morbidities, severity of index condition, views of healthcare options and ability to pay with a correspondingly good fit with the nature and quantity of healthcare consumed. This was the best match of the study and suggests the wide breadth of matching factors needed to ensure good correlation between individuals in terms of healthcare consumption.

Pair G Case 902 and control 52   Index symptom = hot flushes

If Pair F were the best matched in the study, potentially 902 and 52 were the worst. Case participant **902** is a high user of NHS resources at baseline, largely because she was diagnosed with cancer early during the baseline year. In addition, she suffers from cellulitis, lymphodema, hearing problems and carpal tunnel syndrome. To manage the cancer and related conditions, she has many treatments (monthly zoladex, 6 monthly lymphoedema consultations, chi gung, mindfulness, clinical psychology, over the counter supplements) and is open to both biomedical and complementary therapy treatments. She sought a referral for Bristol Homeopathic Hospital because of unmet need around tamoxifen induced hot flushes. Most treatment and service decisions come about because she seems to be on a breast cancer pathway. 902 makes her decisions because she has been severely ill with a potentially terminal disease, trusts her medical practitioners to provide good care and seeks out other healthcare when there are gaps.

A low resource user, control participant **52** has a long term history of hormonal problems such as infertility and the index condition of hot flushes. She also has neuralgia and migraines. She likes to shop around, using her contacts as a consultant nurse. She is looking for skilled, experienced, up-to-date practitioners that offer options, empathy, hope and specialist expertise to meet her current needs. Ideally, they would agree with her treatment preferences, be accessible (geographically with quick appointments) and have had personal experience of the treatments. She is happy to pay privately to secure their services. Although she has taken some over the counter herbal and homeopathic remedies and initiated discussion about the possibility of homeopathy with her specialist gynaecologist, she was happy to discard homeopathy referral when faced with the specialist's reluctance. Her goal is to self-manage. She takes some preventative, over the counter products. She tends to ignore mild new symptoms and if they become more pressing (e.g. recurrent sore throat) she might ask a colleague at the hospital to take a look. However, the condition has to be relatively serious or bothersome to visit the GP because of taking time off work. 52 makes her healthcare choices on the basis of expediency and competency.

In comparing case participant 902 to control participant 52, both have hot flushes, but those of 902 have resulted from a serious illness while 52 has had long term chronic hormonal complaints. Because of her cancer, 902 is more reactive while 52 is highly consumerist in her healthcare approach and well placed to make active, informed choices. Unsurprisingly given their different health statuses, circumstances and dispositions, there is a substantial difference in resource usage.

Pair H Case 975 and control 55 Index condition = hot flushes

A medium NHS resource user, case participant **975** attempts to self-manage, before consulting the GP. She has consulted the GP for a wide variety of minor symptoms such as night sweats, breathlessness, migraine and tennis elbow. She does not like using conventional medication, although she will take pain medication when needed. She has paid for medical homeopathy and private alternative treatment for her shoulder, but she now cannot afford it. She was advised against hormone replacement therapy and so asked for GP referral to Bristol Homeopathic Hospital out of 'desperation' after years of intense night sweats. She says she would use homeopathy for 'anything' and is comfortable with home remedies and over the counter use of medications, but she does not self-treat with homeopathy. 975 makes her choices largely on the basis of perceived potential effectiveness with a tendency towards home remedies and medical homeopathy.

Control participant **55** is a very low NHS resource user (0 visits at baseline), despite several ailments including hot flushes, depression, dyspepsia and shoulder and knee pain. She had a long history of episodes of mental instability which she managed relatively successfully with sporadic periods of anti-depressants until the summer of 2010, when a locum GP who practised homeopathy suggested private homeopathy, meditation and exercise. However, despite ‘transformational’ change that she attributes to this combination, she has not pursued homeopathy for her menopausal symptoms because homeopathy does not make ‘rational, logical’ sense to her. Even though she is a low resource user, her GP would be her first port of call for new conditions. She is not interested in preventative health or self-treating, unless a GP has previously recommended a particular product. Although she has a high status professional job, with her health she acknowledges her passivity and waits for suggestions from her GP and then follows them through. Even when she knows of a suitable conventional treatment e.g. HRT for menopause, she will not suggest this alternative to her GP and instead suffers her symptoms without treatment. She has low expectations of GP care. 55 tends to avoid making healthcare choices, if possible, but when absolutely necessary she will seek out her GP, without much faith in the possibilities of improvement.

In comparing 975 to 55, both have the index condition of hot flushes and are well matched in that they have used medical homeopathy (even though 55 was a control). But whereas 975 makes her healthcare choices with a preference for medical homeopathy and an interest in self-treatment, 55 tends to avoid all type of treatment altogether, unless her symptoms become completely unmanageable.

Clinical perspectives on the quality of matching

To obtain clinical opinions on the quality of matching amongst the eight matched pairs, steering group members, including two academic GPs and one medical homeopath, read synopses the eight matched pairs. These included information about symptoms and condition, age, socio-demographic details, baseline and intervention use of GP consultations and medications and a narrative summarising each individual’s approach to healthcare usage. (see Appendix F) The clinicians were then asked to rate the match between 1 (poor) to 3 (good). These ratings were then discussed in a meeting between all clinicians, the project lead and the research assistant.

Table 13 Clinical views on the quality of matching

Pair	Reviewer 1	Reviewer 2	Reviewer 3
882 & 6	2	2	1
882 & 10	2	2	1
939 & 14	2	1	2
985 & 21	2	2	2
475 & 26	2	2	2
064 & 35	3	2	3
902 & 52	2	3	1
975 & 55	2	3	2

This table shows that there was consistent agreement across the reviewers for two pairs (985 & 21 and 475 & 26). The only pair to score highly with a ‘3’ from more than one reviewer was 064 & 35. One pair (902 & 55) prompted vastly different ratings from the clinicians with a ‘2’, ‘3’ and a ‘1’. The discussions with the reviewers about the criteria they used for rating suggested that each reviewer was using a different lens. For example, one of the academic GPs reported viewing each case ‘holistically’, so she took account of socio-demographic characteristics and how the relationship that each participant had to her health. Another reviewer based his views entirely on how well the symptoms matched, while the third considered both symptoms and condition. Overall, the panel agreed that the match had been ‘good enough’ for five pairs (939 & 14; 985 & 21; 475 & 26; 064 & 35; 975 & 55), as all pairs with a ‘1’ rating were eliminated.

The panel suggested that the chances of improving the quality of matches might be enhanced if individuals were matched for symptom and condition. Matching for symptom without condition means that potentially highly disparate pairs will be matched, but further analysis suggests that the discrepancies in resource use might not be too great, if the condition leading to the symptom occurred several years ago. For example, 902 & 52, 882 & 6 and 882 & 10 were matched for a mixture of tamoxifen induced (902 and 882) and natural (52,6 and 10) hot flushes. The disparity of the matching in terms of severity of condition and resource use is wide for 902 & 52, as 902 was diagnosed with breast cancer during the course of the study. However with the other pairings, 882 actually consumed fewer resources, despite her history of breast cancer several years ago, than her matched controls. Therefore, if the protocol became matching on both symptom and condition, some ‘good enough’ pairs might be eliminated.

Summary of findings from this section

So in looking at the clinical ratings and exploring participant accounts, our initial assumption that similar index conditions would lead to similar levels of healthcare resources that appears overly simplistic. Moreover, even obtaining consensus about what a ‘good enough’ match looks like amongst a small group of clinicians was not entirely straightforward. If we follow the recommendations of the clinical panel and eliminate all pairs that received a ‘1’ rating on the basis that the index conditions were not well matched, (882 & 6, 882 & 10 and 902 & 52), we find that far from the single contributor of the index condition, there are multiple factors influencing the type and quantity of healthcare consumption including:

- Index condition, its severity and perceptions of treatability
- Type, quantity and severity of other conditions
- Previous experience and perceptions of the effectiveness of healthcare treatments and providers
- Personal proclivities (e.g. healthcare treatment and service preferences, perception of choice, attitude towards self-treatment, self-directedness, preference for consultation length, views on complementary therapies)
- Relationship and approach to health (e.g. level of anxiety, prioritising of health, avoidance or pursuance of healthcare consumption)
- Cost
- Accessibility and availability
- Relationship to and quality of available healthcare providers

Moreover, evidence from Pair F (064 & 35) suggests that many of these factors, not just one, have to fit closely to result in approximately similar levels of resource use.

Nonetheless, even with a close match amongst multiple factors, similar levels of resource use may not transpire, as is the case with Pair D (985 & 21). Moreover, every extra matching criterion means that fewer matches are possible. For example, during the control selection stage, we found that matching for the number of GP consultations at baseline led to an insufficient number of potential candidates to recruit as community controls. This makes matching a key difficulty that needs resolving for a larger study to progress.

Key learning points

- Consensus from a panel of clinicians suggests that of the 8 pairs investigated in depth, five were ‘good enough’ matches in terms of index condition. Quantitative analyses found that the 17 pairs were well matched for quality of life and wellbeing at baseline, but not for resource usage.
- Potentially many other factors may affect resource usage that cannot be easily captured at the recruitment stage.
- Matching for symptom without condition means that potentially highly disparate pairs will be matched, but the discrepancy between the two might not be as wide, if the condition leading to the symptom occurred several years ago.
- Matching for resource usage is difficult. Matching on index condition alone will not lead to good enough matching of resource usage at baseline because the relationship between condition and resource usage is not straightforward. Yet using proxy measures of GP consultations or attempting to match on index condition with factors that influence resource use such as co-morbidities will restrict the pool of potential community controls to unfeasibly low levels. if other matching criteria include same GP practice.
- Given the complexity, matching should be carried out by a researcher with a clinical background.
- Devising an effective and robust protocol for matching is essential for the viability of a larger study.

Discussion

Discussion of key findings

The aim of the BISCUIT study was to pilot approaches to economic evaluation of homeopathic packages of care delivered at Bristol Homeopathic Hospital, with the intention of testing the feasibility of developing a large scale study. Throughout this report, we have identified key learning points which will not be reiterated here as they have been amalgamated into Appendix G.

Key findings from the study are that:

1. There were two major challenges in this feasibility study. The first was the low level of recruitment of case and control participants. The approach adopted whereby case participants were recruited directly from the Bristol Homeopathic Hospital without prior recruitment of their GP practice meant that the pool of potential candidates was substantially reduced when GP practice permission was not forthcoming. The second challenge was achieving 'good enough' matching of cases and controls, which also affected the recruitment of controls.
2. Because only 9 of the original 315 potential candidates from the Bristol Homeopathic Hospital were matched with controls, representativeness is questionable.
3. The outcome tools were feasible, acceptable, sensitive to change and appropriate.
4. Cases and controls were well matched at baseline for quality of life and wellbeing, but not for resource usage.
5. Quality of life for case participants improved compared to controls. Wellbeing for case participants also changed significantly for cases compared with controls. However because this was not a randomised controlled study, we do not know if the improvements seen were due to the Bristol Homeopathic Hospital service.
6. At baseline, costs were substantially higher for case participants. There was no difference in resource utilisation in the 12 months after baseline between cases and controls.
7. If these study results were to apply to other homeopathic case and matched control populations, then 90 participants (1:1 matched) would be needed in a larger study to demonstrate that the quality of life and wellbeing improvements generated by homeopathic packages of care are worth their cost. But because case and control participants were not well matched at baseline for resource use, we do not have complete confidence in this figure.
8. Individual variability in resource utilisation for both cases and controls was substantial.

Given these findings, quantitative results should be taken with caution. To explore these key findings further, we discuss each of the research sub-questions below.

Is data extraction feasible?

Although laborious, data collection and extraction was feasible. Data were collected through multiple methods including:

- GP medical records
- Participant questionnaires
- Participant interviews

We found that about 60% of the GP surgeries approached gave permission to access their records. This proportion could have been higher if GP practices had been recruited prior to case participant recruitment and the study had been funded by a national body. As the study was funded by a charity, several practices hesitated over participation. Without national funding, the study was not eligible for the local Primary Care Research Network portfolio and therefore was assumed to be less legitimate. Nonetheless, once permission was granted, the extraction of medical record data was relatively easy and quick (20 minutes per participant).

Participant retention in this study was high. Between the interim report of October 2010 and the close of data collection, only three participants dropped out. Moreover, the majority returned all five questionnaires, possibly because the study administrator regularly telephoned and e-mailed requesting late returns. Similarly, only four of the participants invited to interview did not respond to the request. Thus, retention was not problematic and the collection of data directly from the participants was feasible.

Although there was substantial cross over between GP medical records and participant questionnaires with regards to NHS resource data, which led to decision-making about which source was most reliable, a study objective was to determine the advantages of collecting data from both sources versus relying entirely on just one. However, we found that GP medical records and participant questionnaires gave different information. GP medical records provided a chronicle of NHS resource use over an extended period of time, and so were more robust in obtaining an accurate picture of continuous NHS resource usage. They also provided data unobtainable from participants such as details of laboratory and hospital tests and investigations. But participant questionnaires gave important information on wider healthcare use, such as over the counter medications and private healthcare consumption, which was substantial. In addition, the comparison of participant questionnaires also were useful in cross checking GP medical records, which were not as complete as anticipated. However, relying on participant questionnaires to provide continuous data for NHS resource use would be misleading, as there was considerable overlap and gaps between returns. Ideally, a larger study should include the collection of both sources.

Are the outcome measures acceptable, feasible and appropriate?

Initially, the outcome measures selected for this study included the EQ-5D as the quality of life tool instead of the SF-36. We substituted the SF-36 at the suggestion of an economist.

Despite interview data indicating that participants believed that the SF-36 posed many irrelevant questions, we found that the SF-36 was effective in monitoring changes in quality of life for this population, especially the mental domain, which the EQ-5D is less likely to capture. The Warwick Edinburgh Wellbeing tool was also sensitive to changes and acceptable to participants, in addition to providing useful data to corroborate SF-36 findings. As the findings of this study suggest that homeopathic packages of care have a significant impact on changes in wellbeing and quality of life, we would recommend that a larger study include both scales to capture the greatest range of benefits.

The adapted Client Service Resource Inventory was acceptable to participants, but requires further modification to enhance its use. Importantly, interview data suggested that this tool was quite comprehensive in capturing other types of healthcare resource expenditure. Other tools exist to capture resource usage, but given the extensive testing of this tool, both as a questionnaire for participants and as a data extraction form, we would suggest that further evaluators incorporate our suggestions to adapt the tool piloted in this study for future research with this population.

The obvious gap in this study was the collection of data on changes in health status. Initially, we identified and administered symptom and condition specific tools. However given the low numbers of participants and the spread of conditions, these were abandoned as they would not have been useful for quantitative analysis. Nonetheless, in interviews participants queried the absence of data collection on changes in health status. To capture health status changes with such a disparate population with a wide range of conditions, a generic tool is necessary. One possibility is Measure Yourself Medical Outcome Profile (MYMOP) tool, but this would require further testing.

What characteristics do patients believe are important in their healthcare which can be developed into attributes to use in a discrete choice model?

Bristol Homeopathic Hospital participants identified a range of values of importance in terms of both service and treatment, including longer consultations, convenient location of clinics and positive impact on health. The next step in developing a discrete choice model would be to design a questionnaire to weigh those values.

How will we power the larger study?

Before starting this study, we carried out a power calculation and found that for a larger study, based on 90% power and a 25% reduction in prescriptions, 170 participants (85 in each arm) would be needed. The same assumptions for a 25% reduction in GP attendances found that 300 participants (150 in each arm) would be needed. An objective of this study was to refine that calculation.

If these study results were to apply to other homeopathic case and matched control populations, then 90 participants (1:1 matched) would be needed in a larger study to demonstrate that the quality of life and wellbeing improvements generated by homeopathic packages of care are worth their cost. But because case and control participants were not well matched at baseline for resource use, we do not have complete confidence in this figure.

Why might patients currently receiving homeopathic packages of care continue or stop using other NHS resources?

Our underlying interest in asking this question was learning more about what impacts on resource use. To find out, we broadened the question to include control participants. Fundamentally, we wanted to test whether our initial assumptions about resource usage were viable.

This study was constructed on the supposition that recruitment of those with similar index conditions would lead to similar levels of healthcare resources. We imagined that the relationship between the two would look like the following:

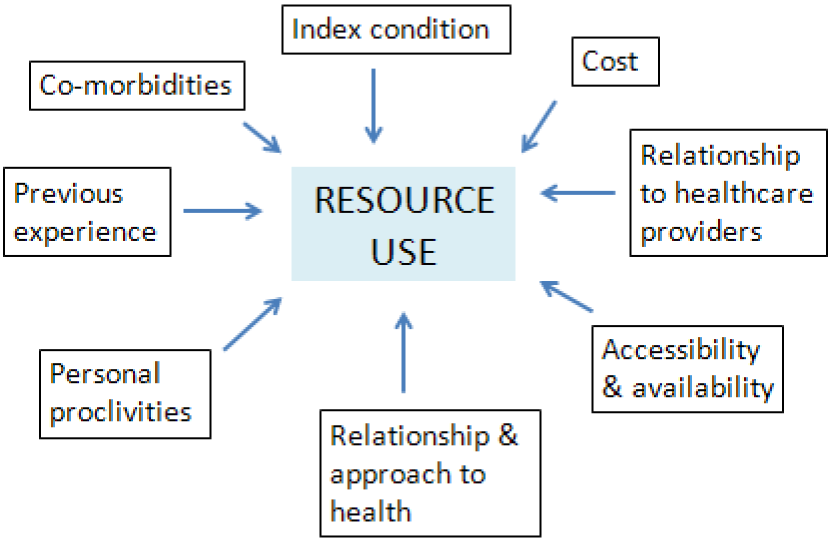
Index condition → Resource use

Instead, far from the single contributor of the index condition, we found multiple factors influence the type and quantity of healthcare consumption including:

- Index condition, its severity and perceptions of treatability
- Type, quantity and severity of other conditions
- Previous experience and perceptions of the effectiveness of healthcare treatments and providers
- Personal proclivities (e.g. healthcare treatment and service preferences, perception of choice, attitude towards self-treatment, self-directedness, preference for consultation length, views on complementary therapies)
- Relationship and approach to health (e.g. level of anxiety, prioritising of health, avoidance or pursuance of healthcare consumption)
- Cost
- Accessibility and availability
- Relationship to and quality of available healthcare providers

So in practice the relationship between factors affecting resource use looks more like the following:

Figure 5 Factors affecting resource use



Thus, the basic supposition behind this study that index condition alone explains resource was found to be overly simplistic. Resource use is much more complicated.

Can we find comparable controls to homeopathic case patients?

As mentioned earlier, finding comparable controls for the case participants is a major challenge for a future study. Matching for GP practice, age within 5 years, sex and index condition was not sufficient to match cases and controls well for resource use. We now know that multiple additional factors affect resource use, and that a high proportion of these factors have to fit closely to result in approximately similar levels of resource use. Nonetheless, we also found that even with a close match amongst multiple factors, similar levels of resource use may not transpire. Moreover, many of these factors (e.g. personal proclivities, previous experience, relationship to health) would not be known to researchers at the time of matching for controls and every extra matching criterion means that fewer matches are possible. Finding enough good quality matches on the basis of resource use is key to the success of a larger study.

Designing a future study

In thinking about designing a larger study, we considered the use of a traditional randomised controlled trial design, which would address known and unknown confounders arising in through matching and lead to the possibility of uncovering a causal connection between the Bristol Homeopathic Hospital service and any changes brought over time. But this type of methodology is difficult to use in evaluating a long-standing service (rather than a treatment) as it does not allow for ‘real life’ decision-making on behalf of patients. There are also ethical issues about denying patients access to an existing, publically funded service, once patients have requested referral.

An alternative could be the use of a Zelens design. In this type of design, the top 20 practices referring into the Bristol Homeopathic Hospital would be recruited first, thereby avoiding the experience in this study of the loss of 40% of participants from GP practice refusal. Then, we would recruit a cohort of patients experiencing the top five conditions treated by the Bristol Homeopathic Hospital from these 20 practices. To recruit case participants, prospective case participants would be sent information about the study as well as baseline questionnaires. Then a researcher would be on the premises of the Bristol Homeopathic Hospital at the time of the first appointment to administer full informed consent, collect completed questionnaires and administer any incomplete questionnaires.

As patients are referred into the Bristol Homeopathic Hospital, they would be matched with community controls from any of the 20 practices on the basis of condition, symptom, age within 5 years and a resource use proxy measure of GP consultations (within 2 consultations) in the past year. The advantages of this approach is that it reflects ‘real life’ by not tampering with patient decision-making and would hopefully lead to much closer matching at baseline between case and control participants. The disadvantages are that without randomisation, known and unknown confounders could affect any observed changes over time and there is no blinding, so this study would be judged as lower quality than a traditional randomised controlled trial. Moreover, we know that individual doctors do vary substantially in their referral patterns, which would impact on patient resource use, and this would not be taken into account in this design. Nonetheless, this Zelens approach would be a step closer to developing a robust study of economic evaluation of the Bristol Homeopathic Hospital.

Conclusion

The intention of this feasibility study was to test the methods and outcome tools to facilitate the development of a larger study. Our over-arching research question was:

> *What are the best methods and best outcome tools for undertaking a large scale economic evaluation of a cohort of homeopathic patients compared with a matched control group not using NHS homeopathy?*

We found that the prospective controlled cohort design may not be the ideal approach, given the difficulties in recruitment and matching case and control participants. But the outcomes tools of the SF-36, Warwick Edinburgh Wellbeing and Client Service Resource inventory were acceptable and useful.

Although undeniably challenging, the importance of designing good quality economic evaluations for generalist services like the Bristol Homeopathic Hospital is important. Therefore, we would encourage future researchers to work through the methodological difficulties to ensure NHS commissioners, and the wider public, have the information necessary to make appropriate judgments of the value of these types of services.

Appendices

Appendix A EMIS record search protocol

Biscuits Data Search

- Open two instances of Emis
  - EMIS1 - to find relevant details
  - EMIS 2 to do your Data Searches

FIRST PATIENT

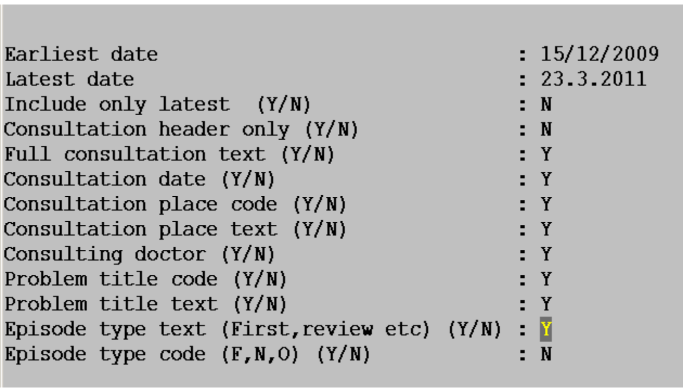
- **Stage 1: EMIS 1**
- Finding the patient's NHS Number
  - F5 – enter patient name
    - Check date of birth is correct (to verify correct patient), return
    - RD write down NHS number

- **STAGE 2: EMIS 2**
  - ST (Search and Statistics) return
  - B (Patient searches) return
  - A (Build and perform a new search) return
  - A (perform search on today's population) return
  - A (add feature) return
  - 12 (RD registration details, you will need to scroll down one page to find this option) return
  - Type in the NHS number you wrote down, return
  - A (shared) return
  - Return
  - Features correct? Type Y
  - Enter name of search (Biscuits and patient ID)
  - Save in suitable place
  - Press to run now

Once search is complete

STAGE 3: EMIS 2

- S (search results)
- Find where you saved your search and return
- Select option F (report names and addresses with aspect etc)
- A (add new report)
- I (consultations)
- Enter the date range given to you



```
Earliest date                              : 15/12/2009
Latest date                                : 23.3.2011
Include only latest  (Y/N)                 : N
Consultation header only (Y/N)             : N
Full consultation text (Y/N)               : Y
Consultation date (Y/N)                    : Y
Consultation place code (Y/N)              : Y
Consultation place text (Y/N)              : Y
Consulting doctor (Y/N)                    : Y
Problem title code (Y/N)                   : Y
Problem title text (Y/N)                   : Y
Episode type text (First,review etc) (Y/N) : Y
Episode type code (F,N,O) (Y/N)            : N
```

- Alter Y and N as above (or as directed)
- I (insert)
- E (present medication)
- A (all)
- Include drug group? Yes
- A (Add aspect)
- F (past medication)
- A (all)
- Include drug group? Yes
- P (Print)
- Word Document
- Return
- Return
- Return
- **On EMIS 2 you now need to press F8**
- Type in the name of the report and return to save this
- Your word document should open up (it should be flashing on your tool bar at the bottom)
- You will now want to print out the word document (and save this to a sensible place). If you can delete past medications that are outside the date range you require (this could save a lot of paper!!)

STAGE 4: EMIS 1

- You should still be on the registration details of your current patient
- Press F1
- MR
- Z
- This will take you to the patient's attachments
- Using your arrow keys press the space bar against eache letter that is within your date range (a star should be next to the highlighted doc)
- Press V and the documents should appear on screen.
- Press print, it should ask you what you want to print, select all loaded documents.
- This is you first patient complete.

All subsequent patients

Stage 1: EMIS 1

- Finding the patient's NHS Number
    - F5 – enter patient name
        - Check date of birth is correct (to verify correct patient), return

        - RD write down NHS number

-
- **STAGE 2: EMIS 2**
    - ST (Search and Statistics) return
    - B (Patient searches) return
    - A (Build and perform a new search) return
    - A (perform search on today's population) return
    - A (add feature) return
    - 12 (RD registration details, you will need to scroll down one page to find this option) return
    - Type in the NHS number you wrote down, return
    - A (shared) return
    - Return
    - Features correct? Type Y
    - Enter name of search (Biscuits and patient ID)
    - Save in suitable place
    - Press to run now

Once search is complete

- **STAGE 3 EMIS 2**
- S (search results)
- Find where you saved your search and return
- Select option F (report names and addresses with aspect etc)
- Now highlight the search you created for your first patient and press return
- P (Print)
- Word Document
- Return
- Return
- Return
- Your word document should open up (it should be flashing on the tool bar at the bottom)
- You will now want to print out the word document (and save this to a sensible place). If you can delete past medications that are outside the date range you require (this could save a lot of paper!!)

- **STAGE 4: EMIS 1**
- You should still be on the registration details of your current patient
- Press F1
- MR
- Z
- This will take you to the patient's attachments
- Using your arrow keys press the space bar against eache letter that is within your date range (a star should be next to the highlighted doc)
- Press V and the documents should appear on screen.
- Press print, it should ask you what you want to print, select all loaded documents.

Appendix B Resource usage questionnaire completed by participants

SPENDING ON YOUR HEALTH

Today's date _____/______/______ *Participant ID number* ________________________________

HOSPITAL INFORMATION

1. In the last 3 months, have you gone to hospital? YES **or** NO

2. Please give details of any visits to A& E in the past 3 months.

	Reason for visit	***If paid for travel, how much did it cost?***
1st visit		
2nd visit		
3rd visit		

3. Please give details of any times you have been admitted to hospital for an overnight stay in the past 3 months.

Admission	***Hospital name, plus department or type of ward*** (e.g. BRIs, neurology)	***Reason for admission***	***Total days***
1st admission			
2nd admission			
3rd admission			

4. Please give details of any outpatient visits you have made to hospital in the past 3 months (e.g. neurology, oncology, psychiatry, day surgery).

	Speciality	***Who did you see eg doctor, nurse?***	***If paid for travel, how much did it cost?***
1st visit			
2nd visit			
3rd visit			

5. In the last 3 months, have you had any of the following investigations or diagnostic tests?

Type of test	Reason for test	Number of times you've had this test in the last 3 months	**If paid for travel, how much did it cost?**
A. Magnetic Resonance Image (MRI)			
B. CT / CAT scan			
C. Ultrasound			
D. X-ray			
E. Electroencephalogram (EEG)			
F. Blood test			
G. Other (please describe) ______________________________			

6. Have you gone to hospital for your health for the past 3 months for any other reason? If so, please give details here.

____

____

____

MEDICATION

7. Please tell us about the medications you have taken in the last 3 months that were prescribed by a doctor (including homeopathic remedies).

	Name	New or repeated medication	Reason for use	How often do you take it?
Medicine 1				
Medicine 2				
Medicine 3				
Medicine 4				
Medicine 5				
Medicine 6				
Medicine 7				

8. Do you pay for your prescriptions? YES **or** NO

9. Please also tell us about any medications that you are taking that are not prescribed by a doctor, for example supplements (e.g. evening primrose oil, vitamins), herbal (e.g. feverfew) or other products for your health that you have used in the last 3 months.

	Name	Cost	Reason for use	How often do you **buy** this?	How often do you **take** it?
Item 1					
Item 2					
Item 3					
Item 4					

GP AND COMMUNITY HEALTH INFORMATION

10. In the last 3 months,

Care provider	Have you had any contact (face to face or telephone) with	How many times have you seen in past 3 months?	Reason for use	If paid for service, how much did it cost?	If paid for travel, how much did it cost?
A. General practitioner (GP)	No Yes				
B. Practice nurse	No Yes				
C. District nurse	No Yes				
D. Community mental health worker eg nurse or doctor	No Yes				
E. Health visitor	No Yes				
F. Pharmacist	No Yes				
G. Psychologist / therapist	No Yes				
H. Counsellor	No Yes				
I. Physiotherapist	No Yes				
J. Osteopath/ chiropractor	No Yes				
K. Occupational therapist	No Yes				
L. Social worker	No Yes				
M. Home help/ home care worker	No Yes				
N. Care attendant	No Yes				
O. Community support worker	No Yes				
P. Housing worker	No Yes				
Q. Voluntary worker (incl priest etc.) Specify _________________	No Yes				
R. Self-help group	No Yes				

11. Have you seen anyone else for your health for the past 3 months? If so, please give details.

____

____

OTHER COSTS

12. Have you had to stop or reduce work due to your state of ill-health? Yes or No

If yes: How many days in the last 3 months? ____________________ *days*

or: How many hours per week less? ____________________ *hours*

13. Did you need a sick note from your doctor? Yes **or** No

14. In the past 3 months, have you lost any earnings because of this time off work? Yes **or** No

If yes: How much gross income (ie before tax) have you lost in the last 3 months?

£

15. In the past 3 months, has anyone in your family lost any earnings to take care of you? Y **or** N

If yes: How much gross income (ie before tax) did they lose in the last 3 months?

£

16. In the past 3 months, have you had any other extra costs of childcare or care of other dependants because of your illness? Yes **or** No

If yes: How much extra costs were incurred for childcare or care of other dependants in the last 3 months?

£

17. In the last 3 months, have you received any help from **friends or relatives** for any of the following tasks, because of your ill health?

Type of help	***Circle***	***Average number of hours help per week***	***Who helped eg partner, friend, mother, father,brother/sister, child***
Child Care *(circle 'No' if you have no children)*	No Yes		
Personal care *(e.g. washing, dressing etc.)*	No Yes		
Help in/ around the house *(e.g., cooking, cleaning etc.)*	No Yes		
Help outside the home *(e.g., shopping, transport etc.)*	No Yes		
Other ________________	No Yes		

A LITTLE ABOUT YOU

17. **Date of birth** ☐☐/☐☐/☐☐ **Age** (years) ___________________
d d m m y y

18. **Marital status** Single
☐
Married/living with partner
☐
Divorced/separated
☐
Widowed
☐

19. **Do you live with** Husband/wife/steady partner
☐
Spouse/partner and children
☐
Children only
☐ Parents
☐
Alone
☐
Other ________________________

20. **Dependants** ____ (number) children < 5 years old
☐
____ (number) children over 5 years
☐
Older relative
☐
Other ________________________

21. **Usual place of residence**

Owner occupied flat/house
☐

Privately rented flat/house
☐

Flat/house rented from local authority or housing association
☐

Other ________________________

22. **What is your nationality**? ____________________________________

23. **What is your ethnicity?** *Please tick one*

☐ Pakistani

☐ Black African

☐ Chinese

☐ Indian

☐ Black Caribbean

☐ White

☐ Bangladeshi

☐ Black other

☐ None of these

24. **Employment status** *Please tick one*

Employed full-time ☐

Employed part-time ☐

Unemployed ☐

Self employed ☐

Retired (because of age) ☐

Not working due to illness ☐

Student ☐

Housewife/husband ☐

Other

____

23 a) ***<u>If you are not working</u>*** Do you receive Incapacity Benefit? Yes **<u>or</u>** No

23 b) ***<u>If you are currently employed</u>***: Occupation

____

Job title

____

Please tick one

Salary before tax less than £10,000 ☐

£10,000-£14,999 ☐

£15,000-£19,999 ☐

£20,000-£24,999 ☐

£25,000-£29,000 ☐

£30,000-£34,999 ☐

£35,000-£39,999 ☐

£40,000-£49,999 ☐

£50,000 or over ☐

23 c) ***<u>If you are unemployed / retired</u>:***

Do you intend to return to work? Yes **<u>or</u>**

No

How long have you been unemployed / retired? *years* _______

*months*_____

Appendix C Adapted tool for medical record data extraction

GP MEDICAL RECORD DATA EXTRACTION

Participant ID number ________________

Medical record data extracted from (date) ____

HOSPITAL INFORMATION

1. In the last year, have you gone to hospital? YES **or** NO

2. Please give details of any visits to A& E in the past year.

	Reason for visit	*If paid for travel, how much did it cost?*	**Date**
1st visit			
2nd visit			
3rd visit			

3. Please give details of any times you have been admitted to hospital for an overnight stay in the past year.

Admission	*Hospital name, plus department or type of ward* (e.g. BRIs, neurology)	*Reason for admission*	*Total days*	***Date***
1st admission				
2nd admission				
3rd admission				

4. Please give details of any outpatient visits you have made to hospital <u>in the past year</u> (e.g. neurology, oncology, psychiatry, day surgery).

	Speciality	*Who did you see?*	*If paid for travel, how much did it cost?*	***Date***
1st visit				
2nd visit				
3rd visit				

5. <u>In the last year</u>, have you had any of the following investigations or diagnostic tests?

Type of test	*Reason for test*	Number of times you've had this test in the last 3 months	*If paid for travel, how much did it cost?*	***Date***
A. Magnetic Resonance Image (MRI)				
B. CT / CAT scan				
C. Ultrasound				
D. X-ray				
E. Electroencephalogram (EEG)				
F. Blood test				
G. Other (please describe) ______________________________				

6. Have you gone to hospital for your health for the past 3 months for any other reason? If so, please give details here.

____

MEDICATION

7. Please tell us about the medications you have taken in the last 3 months that were prescribed by a doctor (including homeopathic remedies).

	Name	Capsule/ Tablet/ liquid	Strength	Amount	Dose	One-off or repeat	If repeat, from when?	Date in med records	BNF code
Medicine 1									
Medicine 2									
Medicine 3									
Medicine 4									
Medicine 5									
Medicine 6									
Medicine 7									

8. Do you pay for your prescriptions? YES **or** NO

GP AND COMMUNITY HEALTH INFORMATION

10. In the last year,

Care provider	Contact?	How many times have you seen in past year?	Dates
A. General practitioner (GP) telephone contact	No Yes		
B. GP practitioner F2F contact	No Yes		
C. Practice nurse telephone contact	No Yes		
D. Practice nurse F2F contact	No Yes		

C. District nurse	No Yes		
D. Community mental health worker eg nurse or doctor	No Yes		
E. Health visitor NOT NEEDED	No Yes		
F. Pharmacist	No Yes		
G. NHS Psychologist / therapist/ COUNSELLOR	No Yes		
H. PRIVATE Counsellor	No Yes		
I. Physiotherapist	No Yes		
J. Osteopath/ chiropractor	No Yes		
K. Occupational therapist	No Yes		
L. Social worker NOT NEEDED	No Yes		
M. Home help/ home care worker	No Yes		
N. Care attendant	No Yes		
O. Community support worker NOT NEEDED	No Yes		
P. Housing worker NOT NEEDED	No Yes		
Q. Voluntary worker (incl priest etc.) Specify __________________	No Yes		
R. Self-help group	No Yes		

11. Have you seen anyone else for your health in the last year? If so, please give details.

____

13. Did you need a sick note from your doctor? Yes **or** No

Number of sick notes

Total number of days covered by sick notes

Appendix D Topic guide for Bristol Homeopathic Hospital participants

Tell me about your experiences of homeopathy

- Why and how did you decide to have homeopathy?
- What did you find of value? E.g. service accessibility and acceptability e.g. frequency of consultations, length of consultations, wait, location, psychological empowerment, side effects
- What didn't you find of value?
- What do you mean by X?
- Did you feel better?
- Expectations of homeopathy?
- Have you used any other complementary therapies? If so what and why? (also for controls)
- Have you had other experiences of homeopathy? (also for controls)

Experiences of taking part in this study

- What led you to taking part in this study?
- Recruitment method – alternative way
- Gimmick – chocolate, "have a cup of tea on us" – do you remember receiving either of these? Did it make a difference to your willingness to take part in the study/ return the questionnaire?
- Reimbursement - £5 voucher – what else could we offer to induce participation and maintain involvement?
- What think of each questionnaire
- Any changes to health not captured by questionnaires?
- Anything else spent her money on not captured by questionnaires?
- Anything else doing/ taking for health physically, mentally, emotionally or spiritually that didn't include on the questionnaire?
- Process of administering questionnaire
    - 3 month frequency – 5 timepoints
    - Postal or other
- How fill out the questionnaire e.g. says 3 months but less than 3 months from previous questionnaire/ look at diary etc.
- Timing of qualitative interview w/in 2-4 months of final questionnaire – appropriate?

Decision making

- When you're ill, what do you tend to do?
- What treatments do you prefer? Biomed, CAM or both?
- When use different services and why?
- Ask about presenting symptom – how is it?
- How are they managing presenting symptom?
- When use different services and why?

Appendix E Topic guide for community control participants

Recruitment

- What led you to taking part in this study?
- Letter of invitation – do you remember who signed it and did it matter?
- Recruitment method – alternative way
- Reimbursement - £5 voucher – what else could we offer to induce participation and maintain involvement?
- Gimmick – chocolate, “have a cup of tea on us” – do you remember receiving either of these? Did it make a difference to your willingness to take part in the study/ return the questionnaire?

Experiences of taking part in this study

- What think of each questionnaire
- Any changes to health not captured by questionnaires?
- Anything else spent money on not captured by questionnaires?
- Anything else doing/ taking for health physically, mentally, emotionally or spiritually that didn’t include on the questionnaire?
- Process of administering questionnaire
    - 3 month frequency – 5 timepoints
    - Postal or other
- How fill out the questionnaire e.g. says 3 months but less than 3 months from previous questionnaire/ look at diary etc.
- Timing of qualitative interview w/in 2-4 months of final questionnaire – appropriate?

Experiences of complementary therapies

- Have you used any other complementary therapies? If so what and why?
- Have you experiences of homeopathy?

Decision making

- When you’re ill, what do you tend to do?
- What treatments do you prefer? Biomed, CAM or both?
- When use different services and why?
- Ask about presenting symptom – how is it?
- How are they managing presenting symptom?

- A year ago, was going to the Homeopathic Hospital one of the treatment options you considered? If no, why not. If yes, why decided not to take up?
- Would you have gone to the Homeopathic Hospital a year ago for this symptom, if it had been offered as an option?

Appendix F Synopses of 8 matched pairs

PAIRS A & B BHH case 882 matched with 6 and 10 (both interviewed)

Summary transcript 882

Interviewed by LW on 5 May 2011 face to face.

Overview

BHH case matched with 6 & 10. Woman, married, aged 53 with two adult sons. Full time nurse specialist nurse earning £30-£35k annually. Lives in owner occupied property in Somerset market town. BHH referral condition = chemotherapy induced hot flushes. Also had dyspepsia and a polyp in her kidney during the study period. Returned all 5 questionnaires. She sees herself as a low resource user, because she sees her GP less than 5 times a year. She gets private healthcare through her job and has used a lot of private resources. Returned 5 questionnaires.

Synopsis

This is the story of a woman who wants easy access to competent healthcare providers who know her history. She achieves this through private healthcare insurance (BUPA) which she gets with her job as a nurse specialist. Mainly suffering from breast problems, including breast cancer, her two most trusted physicians are her private breast surgeon and her oncologist. Her biggest decisions appear to be about the selection of healthcare provider. Once that's in place, she listens to their suggestions, finds out further information (sometimes from research evidence) and then complies, unless she's got concerns about side effects. Once she follows a treatment, she then assesses if there has been an improvement. If not she stops the treatment and potentially no longer contacts the healthcare provider. For example, the GP suggested referral to BHH for her hot flushes, but despite attending 4-5 sessions, she did not notice any improvement and so she has not pursued further contact.

She uses over the counter remedies for minor conditions and in addition to homeopathy at BHH has had hypnotherapy. If a new condition arose, she would hope that it would go away. If not, she said her first port of call would be her breast surgeon. If it were something like a skin condition, then she would consult her GP, although she has little faith that the GPs would treat the condition successfully. Her lack of faith in the GP has been compounded as they recently missed a kidney polph, misdiagnosed as UTI, and the cream they gave her for cellulitis did not help. She does not believe that the quality of care offered by her private providers is better, but her preference for private care is based mostly on the ease of rapid access it provides to a specific healthcare provider that she has known for a long time, trusts and believes is competent.

Given my knowledge of how my American parents use healthcare, this woman's approach is much more American based than I've come across so far.

Summary transcript 6

Interviewed by Lorna on 24 June 2011 face to face

Overview

Community control matched with 65882. Woman aged 51 with chronic back problems, shoulder pain, IBS. Matched on hot flushes, but menopause not mentioned once during entire interview or in questionnaires. Former nurse and carer now retired from ill health. Married with adult children. Lives in rural area in Somerset. Returned all 5 questionnaires. High NHS resource user (14 GP surgery visits intervention year & 13 GP surgery visits baseline year, 14+ medications). Used to see practice nurse more than GP (baseline year) but now sees GP more than practice nurse (intervention year).

Synopsis

This is the story of a woman who uses a lot of healthcare. She visits her GP frequently, partly because her husband and daughter may be tired of listening to her complaints and she has limited other support. She has numerous conditions with new ones emerging, but although she likes her usual GP she doesn't feel that he 'takes her seriously' enough to pick these up. She also has to 'persist' in 'going back', as frequent consultations for the same condition appear to be her way of asking for services. She seems hesitant about making direct requests (ie she wants physio for her back but in 11 years has only broached this with the GP once). Once she is prescribed treatment or given advice, she appears to follow it as instructed. Although not directly asked, given her GP attendance record and her leanings towards biomedicine, it probably is safe to assume that her GP would be her first point of call for new symptoms.

She doesn't rely entirely on her GP for medical advice as she takes on board recommendations from friends and searches websites for information. She uses Vit B and echnicea as preventative medications and mentions that echnicea has some 'proof' behind it, which seems to confirm her actions rather than have persuaded her initially. She had physio delivered acupuncture in a NHS pain clinic and continued with private sessions, which she found beneficial. She also had private grief counselling, which again was beneficial and she appeared happy to pay, although it was the exact same price per session as the acupuncture, which she stopped because acupuncture was too expensive. Several times in the interview she mentions that cost prevents her from taking a particular course of action, which would make sense given that she's on Incapacity Benefit, yet she also takes cruises and regularly visits the US.

Given the lengthiness of her chronic pain and the battery of medications she currently takes, I wonder how much else the NHS, or any healthcare provider, can do for her. The needs of this participant are obviously not currently being met, and they seem to be largely physical rather than emotional, but could any healthcare professional actually meet them?

Summary transcript 10

Interviewed by Lorna on 22 June 2011 face to face

Overview

48 year old, married woman with sciatica and anxiety. Part-time lunch-time school supervisor earning less than £10k annually. Lives in rural Somerset. High resource user (28 GP practice visits + 12 prescriptions baseline; 20 GP practice visits + 8 prescriptions intervention). Matched with 882 and 6 for hot flushes, which are not mentioned once in the interview. Returned 4 questionnaires (possibly 5).

Synopsis

This is the story of an anxious woman who consults the GP surgery most months. There appear to be multiple reasons including: following doctor's orders, seeking advice (and possibly permission?) and monitoring for undetected conditions or to confirm health stability. A key word in this interview is 'check'; she talks about various investigations 'checking' her health status and how she consults the GP to 'check' a particular course of action. She briefly mentions that she doesn't think she's 'worth much'.

She has a particularly good relationship with one GP, whom she credits with finding the right combination of treatments for her panic attacks and anxiety (diazepam, counselling, Tai Chi and working in a charity shop). She appears to be more comfortable with professional advice from the GP, the chemist or even a counter assistant at Holland and Barrett. She recounts two examples of over the counter self-treatment, one which exacerbated the symptoms (witch hazel) and the other (OTC homeopathy) which she half-heartedly says helped. She's not adverse to complementary therapies, but appears to prefer conventional medicine. Even though she's worried about the side effects of prescription medications, these concerns are not sufficient for her to look for alternatives.

Had her GP suggested a referral to BHH, she would have considered it because the recommendation came from her doctor, but as she doesn't drive she probably would not have pursued it. I get a sense that she goes to the GP because the doctor surgery is easily accessible, the doctor is an expert and that's what you do when you don't feel right. Interestingly unlike other accounts e.g. 14 where there seems to be some self-pity, there doesn't appear to be with this participant. She knows the anxiety doesn't make sense, wishes it would go away, but in the meantime is prey to its effects. However, on a more cheerful note, at the time of the interview she had stopped the diazepam, counselling and Tai Chi and the anxiety was manageable.

PAIR C BHH participant 939 and 14

Summary transcript 939

Interviewed by Lorna on 6 July 2011 face to face

Overview

Woman, aged 42, married with 2 children. Living in privately rented flat or house in Somerset market town. Midwife originally from Norway. Variety of conditions including headaches, mood swings, symptoms following a car accident for which she uses a combination of biomedical and complementary treatments. Medium - low resource user (7 GP practice visits + 4 repeat prescriptions baseline; 3 GP practice visits + 4 repeat prescriptions intervention). Uses a lot of other healthcare resources. Uses NHS homeopathy for herself and her children.

Synopsis

This is the story of a woman who believes in combining treatments to maximise their effect. She uses biomedicine to check the seriousness of a condition and when symptoms intensify. But longer term, she'd prefer to use homeopathy and acupuncture to manage her conditions. She is a midwife, but does not self-prescribe or treat others with homeopathy even though she credits homeopathy with bringing on her labour.

In deciding which treatments to use, she considers cost, safety and side effects as well as accessibility in terms of getting fast appointments and being locally situated. She is willing to pay for private treatment, but only if she discerns a benefit that is worth the expense (so she continues with acupuncture but has stopped buying Eye Q supplement).

She has a good, respectful relationship with her GP and her GP is informed and willing to discuss alternative treatments. She doesn't expect more from her GP and rarely consults. However, she does value the questioning and listening of homeopathy, which she thinks has led her to a better understanding of managing her stress. But she is not seeking out the relationship per se, as she hasn't had a consultation in over 9 months.

What's most important to her is that treatments work. Although she is taking some powerful biomedical medications (diclofenac, zomig), she attributes improvements to the complementary therapies. She continues to explore alternatives partly because of her concerns around the safety of biomedical preparations but also because she's interested in mixing and matching to potentise effectiveness. If a particular service or treatment were no longer available, she'd look for something else, preferably complementary. She is an alchemist.

Summary transcript 14

Interviewed by Lorna on 4 July 2011 face to face

Overview

Woman, aged 45. Community control matched with 65939. Arm pain, depression and migraines. In process of difficult divorce, supporting three children, lives in rural Somerset in privately rented house. Exempt from NHS charges halfway through the study, presumably because of low income. High resource user (10 GP practice visits baseline & 6 intervention + 8 repeat prescriptions).

Synopsis

This is the story of a woman who feels she has limited options. Her personal life is very difficult and she has no money. Although she has paid for private acupuncture and private counselling, both during the intervention year of the study, she now sees that her healthcare choices are limited to what is free. If she had been offered NHS homeopathy for either her arm pain or her depression, she would have taken it, despite the travelling, but her GP has not mentioned it.

Although she would like NHS counselling and would be interested in any other service that might help for either condition, currently her treatment options are prescription medications and cheap over the counter preparations such as paracetamol, ibuprofen and a migraine remedy. Her expectations of getting rid of her conditions are low, so she does what she can to diminish the intensity of the symptoms. Managing a decent night's sleep is enough.

In the absence of other alternatives, she regularly consults her GP, primarily for her depression and less so for her pain as she seems resigned that little can help. She doesn't comment on her relationship with her GP, so it is unclear how well her GP is meeting her needs. However, interestingly, she over-estimates how often she uses NHS services such as GP visits and A&E.

If the lack of money were not an obstacle, she would probably use private acupuncture and counselling as she will use non-biomedical treatments, as long as they do not interfere with conventional medications and are safe. But her current circumstances are so bleak that she is not in a position to consider them. This woman is just barely getting by.

PAIR D BHH participant 985 and 21

Summary transcript 985

Interviewed by LW on 21 June 2011 by telephone

Overview

Woman, married, aged 59. Living in rural Somerset in owner occupied residence. Former GP retired for 4 years. Low resource user (3 GP practice consultations + 0 medications baseline; 1 GP practice consultation + 1 repeat med intervention).

Previous minor professional interest in homeopathy. Suffers from bigeminy and arrhythmia that affect her sleep. Returned 5 questionnaires.

Synopsis

This is the story of a retired GP with an untreatable condition who tried NHS homeopathy because nothing else had worked. Given her background and training, unsurprisingly her orientation is towards biomedicine. Although her GP would be her first port of call, she only seeks medical attention when she doesn't know what is happening or when she knows she needs treatment. Otherwise, her tendency is *to let nature take its course.*

However, she supports NHS homeopathy and knows enough from her own homeopathic prescribing to be familiar with the basic principles of treating the whole person. She believes homeopathy has a role for people with conditions that do not respond to conventional medications or for which there are limited options, like herself. Even though her own homeopathic treatment was only partially successful, she would continue to support NHS homeopathy as her opinions are formed less by personal experiences of benefit and more from professional wisdom of the limitations of healthcare, whether homeopathic or conventional.

There is some suggestion in the data that she feels quite alone with her condition. She talks about the difficulty in not being able to discuss her homeopathic treatment with her GP, being 'left really' if the remedy doesn't work and the misfortune of waiting nearly a year between her first appointment at BHH and her follow up. Although she has re-initiated contact with BHH, she doesn't appear to have great expectations of improvement. She's not desperate and she seems resigned to living with her symptoms.

Summary transcript 21

Interviewed by Lorna on 27 July 2011 by telephone

Overview

Woman, married with adult daughter who lives locally. Lives in rural Somerset in an owner occupied property. Retired, aged 63, although sounds older. Medium resource user (8 GP practice visits + 0 medications baseline; 5 GP practice visits + 2 medications intervention). Dutch background. She says she has got *a nice, comfortable life*. Heart palpitations from a genetic disorder, borderline hypothyroidism.

Synopsis

This is the story of a married, retired woman living in the country who has got 'a nice comfortable life' with a husband, family, friends and outside interests. She and her husband appear to have developed a joint approach to healthcare where they rely mainly on bulk over the counter herbal remedies for minor conditions and prevention (e.g. echnicea for coughs and colds, ginko for memory loss), although she doesn't seem particularly knowledgeable about the different products. Other health related activities have a social element e.g. yoga for balance, golf for exercise, ramblers for her husband’s knee, none of which is recorded on the resource form so perhaps her perception is that these are primarily meeting non-health related needs.

She consults a GP when she is unfamiliar with the condition, when her chronic condition deteriorates, with new, more serious symptoms and when she experiences side effects from her medication. She may stop taking medication if she doesn’t like the side effects or she doesn’t think the medications are helping, sometimes without informing her GP. For example, the beta blockers for her heart palpitations are not giving her side effects and her palpitations, although currently getting slightly worse, are better than before so she will continue to take them. In contrast, she had no symptoms of hypothyroidism and doesn’t notice any difference with the thyroxine, and she appears to be waiting for the next blood test to decide whether to continue taking thyroxine.

She doesn’t appear to want close, frequent contact with her healthcare providers. She likes her GP, but doesn’t consult very often. She likes complementary medications, but doesn’t seek practitioner based care, partly because she sees it as expensive. She would have followed up referral to the BHH, if her GP had suggested it, despite the long distance because she is curious about complementary therapies, not because she has unmet health needs. Rather her need for healthcare seems to be instigated by changes in physical health, based largely on finding relief for symptoms that interfere with her daily life. At the moment, she’s fine.

PAIR E BHH participant 475 matched with 26

Summary transcript 475

Interviewed by LW in June 2011 face to face.

Overview

Woman, aged 50, married with two teenage children, living in outskirts of Bristol. Part-time hospital chaplain earning between £10-£15k annually. Low resource user (4 GP practice contacts + 1 prescriptions baseline; 3 GP practice contacts + 1 medications intervention). High user of chiropractic. 4 questionnaires returned. Matched with 22-26. Referral condition = hot flushes. Also suffers from high blood pressure, breathing problems and palpitations.

Synopsis

This is the story of a woman with hypertension, palpitations, menopausal symptoms and breathing difficulties who believes that she reacts badly to biomedical preparations and so has minimal options. As a result, her aim in attending BHH is to reduce her dependence on conventional drugs. She is happy with biomedical care for diagnosis but prefers homeopathic treatment and credits attendance at BHH with her minimal resource use. She understands that homeopathy looks at the 'whole person' and so she uses it for multiple conditions simultaneously. She has been attending BHH for the past 6 years.

Although she does not call on her GP services much, her overall healthcare resource use is relatively high. She takes several over the counter preparations (e.g. Vit E, starflower oil, calcium) and sees a chiropractor for an old whiplash injury every six weeks. She would pay for private homeopathic treatment. Although she is loathe to take conventional medications, the same aversion is not true for homeopathic remedies or over the counter products as she hasn't had a reaction to homeopathy and believes that supplements are 'natural' and already exist in the body. Although I didn't completely understand this, her belief appears to be that the body has a 'reservoir' where it stores beneficial products such as supplements and homeopathic remedies to call on when needed. The same does not appear to be true for conventional medication.

Nonetheless, her GP would be her first port of call for a new symptom, unless it was related to her back when she would call on her chiropractor. In comparing her consultations with her GP to those with her homeopath, for example with hypertension, she observed that the GP defined the 'problem' as high blood pressure which needed hypertensives while the homeopath defined the 'problem' as stress, which needed to be identified and reduced. However, she's not entirely clear if the remedies consistently work. Nonetheless, she doesn't feel that conventional medications are an option, so her only recourse is homeopathic treatment, whether at the BHH or privately, and 'natural' over the counter preparations.

Summary transcript 26

Interviewed by Lorna on 15 August 2011 face to face

Overview

Woman, aged 50, married without children. Full time personal assistant earning between £20-£25K. Living in eastern suburb of Bristol. Matched with 62475 for menopausal symptoms. Low resource user (2 GP practice contacts + 1 prescription baseline; 3 GP practice contacts + 2 medications intervention). Returned 4 questionnaires, missing final. Suffers from sciatica and menopausal conditions.

Synopsis

This is the story of a pragmatic woman who rarely uses NHS services for several reasons. She views her ailments as minor; she believes that GP treatment is largely limited to prescription medication; she finds it difficult to get an appointment with her GP and once she decides to have treatment, she doesn't want to wait. When a condition arises, except for her ears which she seeks help for quickly as she's clinically deaf, she usually waits for the condition to clear up on its own or goes to the chemist for something over the counter, possibly recommended by a friend. If that doesn't work, she will then seek GP services (ie HRT for menopause) or in the case of sciatica where she knows a suitable practitioner she will pay for private treatment (ie physiotherapy).

She normally avoids medication because she believes that they 'mask' the symptoms and there is some suggestion that she is worried about psychological addiction. So seeks other kinds of treatment, where possible. She rates physiotherapy highly because she's found it effective on two different occasions. After unsuccessful experiences with over the counter herbal preparations, she sought HRT because of symptom severity and a change in her circumstances which meant she couldn't employ her usual coping mechanisms. She takes a few over the counter preventative supplements such as Omega 3 for joints and evening primrose oil for menopause, but she is not entirely clear if they work.

Her inclination is towards biomedical treatments, especially for serious conditions like cancer, although she says she would consider acupuncture or chiropractic as they are more mainstream. She sees complementary therapies as 'having a place', for example the over the counter herbal remedies were appropriate for night waking and sweats because menopause is not something that needs 'curing'; instead she wanted 'a bit of a boost'. Despite knowing nothing about homeopathy, she would have taken up a referral to BHH, if it had been suggested by her GP, as she wanted to avoid medication, if possible. But she actively asked for HRT in her GP consultation and the GP did not suggest alternatives. She doesn't seem to have or want a particularly close relationship with her GPs, whom she says are 'brilliant'. It's enough that they 'come up trumps' when she does visit.

PAIR F BHH participant 064 matched with 35

Summary transcript 064

Interviewed by Lorna on 28 Sept 2011 by telephone

Overview

Woman, aged 57, divorced, no children. Self-employed therapist earning less than £10k annually. Lives in Somerset market town. High resource user (21 GP practice contacts + 5 prescriptions baseline; 14 GP practice contacts + 8 medications intervention). Matched with 35 for chronic fatigue. Also has back problems, IBS, thyroid condition, basal cell carcinoma. Returned 5 questionnaires.

Synopsis

This is the story of a woman who is anxious about her health and consumes a lot of NHS and private healthcare, despite being on a low income. She worries about hidden, not easily detected causes of ill health such as viruses and environmental contaminants. In giving her account, she often cannot remember the reason for taking a particular treatment or whether it had a beneficial effect, perhaps because she's tried so many. There is some suggestion in the data that fundamentally she thinks there is something wrong with her.

To help, she wants long consultations so she has enough time to disclose and 'work out' in collaboration with her practitioner what is going on. She is much more likely to receive long consultations (and possibly greater acceptance of the hidden) from private practitioners. She wants someone who accurately diagnoses and treats competently. So for example, she appears disappointed with her GP and her biomedically trained environmental doctor as they did not initiate investigations into thyroid imbalances when she complained of tiredness. In contrast, she highly rates her herbalist who suggested that she take thyroxine despite the borderline test result and she felt better. The herbalist is currently treating her both on the NHS and privately with a battery of herbs for her 'viral load'.

She does a lot of her own research online and from books, buys over the counter products and is happy to self-treat. Her first response to a new condition would be 'panic' followed by looking for information. Then she would consult her herbalist, the GP or self-treat, depending on the condition. She thinks her GPs are very 'warm', 'caring' and 'open minded' but they would only be her first port of call for infections or in an emergency.

Although she 'passionately' believes in homeopathy and initiated the referral to BHH, she wasn't particularly satisfied with her BHH experience as the follow up consultations were too short and she wasn't sure that the remedies made a difference. She also does not follow up on every referral, as she received a referral to the chronic fatigue clinic which she didn't take up.

This is a woman who possibly views her health as puzzle, so she needs the expertise of and time with competent practitioners to work out what the next piece is and where it goes.

Summary transcript 35

Interviewed by Lorna on 2.9.11, 7.9.11 and 13.9.11 by phone. Multiple short conversations over several days because of illness and fatigue of participant.

Overview

Woman, aged 49, single living in local authority or housing association property. Receives Incapacity Benefit. Lives in Somerset market town. Not worked for 18 months due to ill health. High resource user (21 GP practice contacts + 6 prescriptions baseline; 14 GP practice contacts + 5 medications intervention). Matched with 35 for chronic fatigue. Also has digestive problems, menopausal symptoms, thyroid irregularities, back problems, insomnia. Returned 4 questionnaires. Envelope for 5th questionnaire arrived in September 2011, but nothing was inside.

Synopsis

This is the story of a woman with chronic fatigue who uses a lot of healthcare. Because she needed to stop, the interview took place over three different occasions. For this reason and possibly because she is so ill, I found it hard to identify a way into her story.

I know she uses complementary and NHS healthcare resources indiscriminately and will try anything recommended from healthcare practitioners, friends, over the counter assistants and even leaflets. I know having experienced many treatments e.g. acupuncture, herbal medicine both privately and in the NHS, she appreciates the extra time from private consultations but the expense is a consideration. I also know that she's found the lightening process, with its emphasis on self-management and hope, the flower essences and nutritional treatments most helpful. However, the lightening process course was over 2 ½ years ago, so I'm not sure if it can be credited with her reduction in NHS resource contact over the study period. So she doesn't seem to be particularly looking for 'medical attention' or a close relationship with her practitioner; I think she just wants to feel better.

She says she would self-treat as a first response to a new condition and then see her GP. She might have accepted a referral to BHH, although she may have got that confused with the system for NHS access to complementary therapies at her GP surgery because she thought she had had her 'lot'. She has had 'complex' homeopathy before from a private practitioner who was a former GP, which she thinks made a difference but she is not sure whether 'normal bog standard' homeopathy is effective.

She mentions several times wanting to be ‘at peace’ with herself. I think there is much more to this story that unfortunately because of circumstances, we couldn’t get.

PAIR G BHH case 902 matched with 52

Summary transcript 902

Interviewed by LW in early April 2011 Face to face

Overview

Woman, single, aged 44 living in council or housing association property. Part-time finance worker. High resource user (22 GP practice contacts + 7 prescriptions baseline; 20 GP practice contacts + 13 medications intervention). Completed all 5 questionnaires. Referred to BHH for tamoxifen induced hot flushes. Breast cancer detected in baseline year May 2009. Also suffers cellulitis, lymphodema, hearing problems, carpal tunnel syndrome and suspected glaucoma. Matched with 52 (interviewed) and 51 (not interviewed).

Synopsis

This is the story of a woman who recently had breast cancer and is still coping with the after effects. As a result, she has many treatments (monthly zoladex, 6 monthly lymphoedema consultations, BHH homeopathy, chi gung, mindfulness, clinical psychology, over the counter supplements) to help control the cancer, its side effects or its ramifications or to bring her back into good health. She appears happy to use either complementary or biomedical treatments. Although she never says this, I get the sense that she’s willing to try anything; she could be very frightened.

Most treatment and service decisions come about because she seems to be on a breast cancer pathway where X or Y is recommended and so she complies. There is not much here about proactive choice but rather routine use of healthcare with the occasional word of mouth recommendation, which she follows up.

Her homeopathy referral came about at the prompting of her oncology registrar, although she reports that she was interested beforehand. She initially sought homeopathy only for the treatment induced hot flushes, although she also hoped it would help the cellulitis.

Some themes from previous participants re-appear in this account such as : 1) checking to monitor current conditions or to identify previously undetected conditions (e.g. hearing test, diabetes, glaucoma, high blood pressure) 2) combining treatments to maximise effects, 3) valuing the questioning of a BHH consultation.

She makes a distinction between her resource use several years ago, when she reports she rarely sought GP or other services, and now, where she is firmly entrenched in the system. She dates it to 4-5 years ago, which was a couple of years before she was diagnosed with cancer. Given that this pre-dates her cancer, why did her healthcare seeking behaviour change?

Summary transcript 52

Interviewed by Lorna 23 August 2011 by telephone

Overview

Woman, aged 41, single. Hospital consultant nurse. Matched with 902 for hot flushes. Also has had fertility problems, neuralgia in her arms and legs and migraines. Mentions a 'cardiovascular condition' but no other details. Low – medium resource user (4 GP practice contacts + 2 prescriptions baseline; 3 GP practice contacts + 5 medications intervention). Completed all 5 questionnaires.

Synopsis

This is the story of a consultant nurse that likes to shop around. She's looking for skilled, experienced, up-to-date practitioners that offer options, empathy, hope and specialist expertise to meet her current needs. Ideally, they would agree with her treatment preferences, be accessible (geographically with quick appointments) and have had personal experience of the treatments. Once identified, she's happy to pay privately to secure their services. To find the right practitioner, she uses her contacts as a healthcare professional.

Although she says that she considered homeopathy for her hot flushes and has taken some over the counter herbal and homeopathic remedies, her actions suggest that she is more attuned to biomedical treatments and so was happy to discard homeopathy referral when meeting the reluctance of her specialist gynaecologist. In discussing what has helped in the past, despite using a range of complementary therapy treatments like chiropractic, herbal medications and reflexology, she only mentions biomedical interventions.

Her goal is to self-manage. She takes some preventative, health enhancing over the counter products (beroca to avoid colds and omega 3 for 'brain power'). She tends to ignore mild new symptoms and if they become more pressing (eg recurrent sore throat) she might ask a colleague who specialises in that area at the hospital to take a look or consult her GP. However, the condition has to be relatively serious or bothersome to visit the GP because of taking time off work.

This woman who knows what she wants and will spend considerable resources in finding and securing it.

PAIR H BHH participant 975 matched with 55

Summary transcript 975

Interviewed by LW on 6 July 2011 by telephone

Overview

52 year old married woman who has had menopausal symptoms for about 10 years. Teaching assistant with two children aged 22 and 24 earning less than £10k annually. Lives in village in South Glos. Had 3 BHH appointments. Medium to high resource user (7 GP practice visits baseline; 8 GP practice visits intervention + 2 repeat prescriptions). All 5 questionnaires returned.

Synopsis

This is the story of a woman who would like to more medical homeopathy to be available on the NHS. Having been successfully treated for two conditions by different medical homeopaths, her ideal would be a trained GP homeopath at her GP practice. She was advised against hormone replacement therapy and so asked for GP referral to BHH homeopathy out of 'desperation' after years of intense night sweats. She values homeopathy for the questioning and time, which helped her to become more aware. However the main benefit is relief from her physical symptoms, which have largely gone.

When symptoms arise, she first attempts to self-manage with over the counter medications or home remedies (ie cider and honey for sweats), before consulting the GP. Over the past two years, she has consulted the two GPs at her surgery for a wide variety of minor symptoms such as night sweats, breathlessness, migraine (GP said all associated with menopause) and tennis elbow. The female GP tends to respond with testing and no treatment, while the male GP gives injections and had made a hesitant suggestion of a private alternative practitioner. However, she doesn't like using conventional medication (although she will pain medication when needed), so perhaps the GPs have limited options. She seems to have a perfunctory relationship with her GPs, but doesn't give an indication that she's looking for anything more than diagnosis and symptom relief.

There are some inconsistencies in her account. She presents herself as an informed patient who assertively asks for referral to BHH from a reluctant GP, but then she also gives several accounts in which she plays a more passive role (e.g. her GP – not her – wants to carry out diagnostic testing when she loses her voice with the flu and when she mentions 'in passing' her breathlessness.) She has paid for medical homeopathy in the past and would again and pays for private alternative treatment for her shoulder, but she also says she can't afford it. She says she would use homeopathy for 'anything' and is comfortable with home remedies and over the counter use of medications, but she doesn't self-treat with homeopathy. This doesn't appear to be because she's invested in the F2F relationship with the homeopath, because it's been 10 months since her last consultation. Perhaps she either does not know it is possible to self-treat with homeopathy or she does not have the confidence. So although she says she wants more homeopathy in her healthcare portfolio, this appears to be in terms of F2F contact with a medical homeopath, although it doesn't appear that what she's seeking is the relationship.

Summary transcript 55

Interviewed by Lorna on 1 August 2011 face to face

Overview

Woman, married, aged 54 with two children aged 22 and 24. Full time deputy head of a school earning £50k+. Lives in owner occupied residence in rural S Glos. Although selected as a community control, she actually accessed F2F homeopathy from a medical homeopath during the course of the studyWrote a lot of extra information in her questionnaires. Returned 3 questionnaires, the last one she handed over at interview. Low resource user ie didn't use any NHS resources at all in baseline year and only saw GP once in intervention year. Suffers from menopausal symptoms, depression, dyspepsia, shoulder and knee pain.

Synopsis

This is a story of a woman who does not want to be seen as 'loopy doopy'. She's had a long history of episodes of mental instability which she managed relatively successfully with sporadic periods of anti-depressants until the summer of 2010, when a locum GP who practised homeopathy suggested private homeopathy, meditation and exercise. Except for a 'dip' in November 2010, she's found the combination 'transformational' as has her son. However, these first hand experiences have not made her a homeopathy 'believer' and she has not pursued homeopathy for her menopausal symptoms. Homeopathy does not make 'rational, logical' sense to her and she prizes being rational and logical.

Even though she is a low resource user, her GP would be her first port of call for new conditions. She is not interested in preventative health or self-treating, unless a GP has previously recommended a particular product. Although she has a demanding professional job, with her health she acknowledges her passivity in that she waits for suggestions from her GP and then follows them through. Even when she knows of a suitable conventional treatment e.g. HRT for menopause, she won't initiate this discussion with her GP and instead suffers her symptoms without treatment.

She has low expectations of GP care, believing that each GP has a particular condition which they treat well (ie one GP helped her with her depression but not her menopause, another was good for her shoulder but not her depression) and if the suggestions don't work, she tends not to re-consult. She was very grateful to the GP who gave her a metaphor to understand her depression better and speaks highly of him; but gives mixed reviews of the locum GP homeopath who successfully treated her depression whom she describes as 'smug' but also 'a decent GP'. She values practitioners who help her to see her condition or situation in a new light but she is not attached to the relationship.

This woman gives discrepancies in her accounts of what she did, when and why, yet also values consistency, stating that she likes to go back through her questionnaires when completed to check for consistency.

Appendix G Compilation of key learning points

1. The process of scheduling re-visits should start about two weeks before the anniversary of the first case appointment.
2. Holidays and the coinciding of several anniversary dates during the same time period can substantially affect the re-scheduling of visits.
3. Further delay in re-scheduling visits can come about if the original staff member has left the practice and the process of relationship building needs to start anew.
4. Case site files with the relevant patient consent forms, study information sheets and R&D approvals should accompany the researcher on each visit. A researcher also needs to bring along a heavy black pen, a set of scissors and folders for the records.
5. The best way to collect the data is to download all of the relevant information while on GP surgery premises, print it and take it away, once it is anonymised. This then gives the researchers the opportunity to extract, cross reference and input the relevant data at leisure.
6. Practices are unlikely to let a researcher have direct, unsupervised access to their IT systems.
7. Sending data electronically is difficult, because of the problems in accessing NHS Net, and may challenge data protection guidelines.
8. Although visiting practices is time consuming, personal visits do ensure that all the data required are downloaded and that the GP staff member makes time to carry out this task.
9. If everything is running smoothly, it takes about 20 minutes to download, print and anonymise one set of medical records.
10. Only a third of the practices took up the offer to be financially reimbursed for their time, most basing their charges on time spent. However, if practices charge per record, the costs are higher per record.
11. Maximising personal contact between the study team and the participants is helpful, so ringing, e-mailing or texting participants to ask for return of questionnaires worked well.
12. Monitoring the administration of the questionnaires through an Access database was helpful. Ideally, data from questionnaires should be entered as soon as possible after receipt.

13. The process of extracting GP medical record data was time consuming and laborious but yielded a rich quantity of information on NHS service usage, some of which was not obtainable via participants (e.g. laboratory tests).

14. Data cannot be directly extracted from GP medical records and input into a study database as considerable time is needed for checking and cross checking information across the records and then between the records and the participant questionnaires. For this reason, obtaining copies of the medical records is advisable.

15. The data from GP medical records that appear to be robust and trustworthy are:
    a. GP and practice nurse consultations
    b. Hospital out-patient consultations delivered by a doctor
    c. Minor injuries unit
    d. Hospital in-patient admissions
    e. Hospital tests with documented results
    f. Laboratory tests

16. Prescription data from GP medical records was surprisingly not that trustworthy. Medications prescribed by hospital consultants were often not listed in GP medical prescription charts while repeat medications prescribed by GPs sometimes were also left unrecorded.

17. GP medical records for community clinics and non-doctor hospital visits were often incomplete. This could be picked up more explicitly in the participant questionnaires.

18. Both the participant questionnaire and the GP medical record extraction tool should be revised before carrying out a larger study.

19. Given the overlap and gaps in participant questionnaires, relying on questionnaires to provide continuous data over several time points would be inadvisable. Only GP medical record data can provide continuous information over a study period.

20. Ideally, both participant questionnaires and medical record extraction should take place to ensure more accurate collection of NHS service usage. Neither source on its own provides a complete picture. The advantage of drawing on both sources is that some queries can be resolved, although occasionally discrepancies also emerge.

21. To recruit BHH participants for a future study, the BHH secretaries could send out invitations, participant information sheets, consent forms and possibly

health status and quality of life questionnaires? to new patients at the BHH along with their first appointment confirmations. A researcher would then be on hand on the premises at BHH at the first appointment to carry out written consent, collect completed questionnaires and administer any incomplete questionnaires. Hopefully this would enhance the quality of responses received and build longer term commitment to the study.

22. The consent form should include an option for questionnaire format preference - electronic or postal. Postal questionnaires should be checked to make sure that the layout has not been disturbed in printing. Administrating questionnaires every 3-4 months is about the right frequency. All returned questionnaires should be read by the researcher when they come in to pick up on any problems or answer participants' queries.

23. The vouchers were perceived as messages of thanks, appreciation and payment. They were popular and should be incorporated into the design of any future study. The teabag and chocolates might not be as useful.

24. We need greater clarity on what resource use we would like recorded. The issue is that the resource questionnaire gives information not only about costs and but also about treatments. So for example, it would be useful to capture 'free' complementary therapy consultations like reiki, as that gives an indication of complementary therapy use, but knowledge of other free activities like walking would be less useful.

25. The resource questionnaire, quality of life questionnaire or 'a little about you' could go first as they may be easier to answer. A box for 'is there anything else you want to add?' should be included for those who like to explain their answers or add extra information. The resource questionnaire needs to be modified to capture day surgery, private healthcare resource use, private medical, non-medical and over the counter homeopathy, private and NHS counselling. Given that participants reported checking their medication bottles to complete the medication, we could ask for more specific information on strength and form to more accurately price prescriptions. To capture no cost interventions and spiritual and exercise health related activities, include the question 'is there anything else you do physically, emotionally, mentally or spiritually for your health or wellbeing?

26. Although participants queried the usefulness of SF36 and the wellbeing tool, quantitative analysis found that the data collected did capture changes. Moreover, the use of both tools with similar results validated those findings. Therefore, SF36 and the wellbeing tool appear to be appropriate for the Bristol Homeopathic Hospital population. The resource questionnaire is fairly comprehensive in encouraging respondents to record a wide range of

resource usage and with modifications would also be useful in a larger study. Capturing health outcomes in a tool such as MYMOP could be useful.

27. The attributes of top value to Bristol Homeopathic Hospital participants were extended consultation length, positive impact on health and convenient location.
28. Consensus from a panel of clinicians suggests that of the 8 pairs investigated in depth, five were ‘good enough’ matches in terms of index condition. Quantitative analyses found that the 17 pairs were well matched for quality of life and wellbeing at baseline, but not for resource usage.
29. Potentially many other factors may also affect resource usage that cannot be easily captured at the recruitment stage.
30. Matching for symptom without condition means that potentially highly disparate pairs will be matched, but the discrepancy between the two might not be as wide, if the condition leading to the symptom occurred several years ago.
31. Matching for resource usage is difficult. Matching on index condition alone will not lead to good enough matching of resource usage at baseline because the relationship between condition and resource usage is not straightforward. Yet using proxy measures of GP consultations or attempting to match on index condition with factors that influence resource use such as co-morbidities will restrict the pool of potential community controls to unfeasibly low levels, if other matching criteria include same GP practice.
32. Given the complexity, matching should be carried out by a researcher with a clinical background.
33. Devising an effective and robust protocol for matching on resource usage is essential for the viability of a larger study.

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