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ORIGINAL PAPER

A patient reported outcome measure in homeopathic clinical practice for long-term conditions

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Background: **This study was initiated as part of a quality improvement audit process to create standards around goal setting with our patients to understand and improve outcomes of homeopathic treatment.**
Method: **We used the Measure Yourself Medical Outcome Profile (MYMOP2) as a tool to assist clinicians in setting the treatment goals across a wide range of diagnoses and other complaints in routine clinical practice at the Bristol Homeopathic Hospital. The data collected from the MYMOP2 is of significance in its own right and the results are now reported in this paper.**
Results: **A total of 198 patients with a wide range of complaints attended one to five consultations with 20 homeopathic doctors. Diagnostic categories were most commonly neoplasms (16.7%), psychological (13.9%) and genitourinary complaints (12.3%), with 66.7% suffering from these problems for at least one year. The three symptoms that bothered patients the most were pain, mental symptoms and tiredness/fatigue. A paired-samples t-test using an intention-to-treat analysis showed that the MYMOP2 profile score improved from 4.25 (IQR 3.50–5.00), with a mean change of 1.24 (95% CI 1.04, 1.44) from the first to the last consultation ($p < 0.001$). Results were statistically significant both for completers ($n = 91$) ($p < 0.001$) and non-completers ($n = 107$) ($p < 0.001$) using last-observation-carried-forward, although completers did better than non-completers ($p < 0.001$). The overall clinical significance of improvements was at least moderate. A repeated measures ANOVA test also showed statistically significant improvements ($p < 0.001$).**
Conclusion: **The MYMOP2 results add to a growing body of observational data which demonstrates that when patients with long term conditions come under homeopathic care their presenting symptoms and wellbeing often improve. Offering a low cost high impact intervention to extend the range of choice to patients and to support self-care could be an important part of the NHS.** *Homeopathy* (2016) **105**, 309–317.

Keywords: Homeopathy; MYMOP; Long term conditions; Self-care

Introduction/Background

The Bristol Homeopathic Hospital (BHH), at the time of this study, was part of a large NHS foundation trust working on creating standards around goal setting with our patients to understand and improve outcomes of homeopathic treatment. The aim has also been to communicate goals and outcomes more effectively to referring colleagues and

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commissioners of the service. A standard setting initiative carried out within the unit and linking to other UK homeopathic hospitals used a patient reported outcome measure, the Outcome in Relation to Impact on Daily Living (ORIDL) and it was found to be useful for assessing outcomes in a large population of patients.[26] In this paper we present the outcomes of the Measure Yourself Medical Outcome Profile (MYMOP2)[16] data collected as part of a quality improvement audit submitted to the clinical audit department at University Hospitals Bristol NHS Foundation Trust.

Choice of outcome measure

ORIDL used in the standard setting initiative is an exit score where patients, with the help of their doctor, rate any improvement or deterioration of the presenting complaint over a package of care using a seven point numerical rating scale. The number of visits in a package of care vary from unit to unit. The BHH service introduced a package of care of one new patient consultation of one hour, plus four 20 min follow-up consultations spaced every 6 weeks to 6 months depending on clinical need. One limitation of ORIDL is that it does not have a baseline, so comparison of symptoms from before to after an intervention relies on recall. We therefore used the Measure Yourself Medical Outcome Profile (MYMOP2). As well as introducing a baseline score which helps to improve the credibility of changes in patients' symptoms, MYMOP2 encourages doctors to identify what patients experience as their most problematic symptoms, and records changes in those symptoms over time. This has the potential for doctors to use this information to set goals and report outcomes as a measurable response.

MYMOP2 supports an approach that values both conventional and complementary treatments which has been termed Integrative Medicine (IM) and is championed by the UK homeopathic hospitals. It has been extensively used in the integrative care setting,[20] in conventional care[17] and complementary and alternative medicine (CAM) settings.[4] It has been used to assess patients' experiences after treatment with acupuncture (e.g. Ref. 4), massage (e.g. Ref. 18), homeopathy (e.g. Refs. 2,11), and conventional medical treatment (e.g. Ref. 17).

MYMOP2 is a patient generated measure that has been validated against other quality of life measures such as EQ-5D, MOS-6A and SF-36.[10,16,19,20] Patients are asked to volunteer the two most troublesome symptoms associated with their condition, plus an activity score and overall wellbeing score, all measured on a seven point numerical rating scale. A complaint may be a diagnosed disease, such as asthma or chronic fatigue syndrome, or an undiagnosed healthcare problem such as difficulties in breathing or lack of energy. Diagnoses and complaints often consist of several symptoms. The outcomes for these symptoms are tracked over time. This encourages and facilitates a more realistic setting of goals that relate to symptoms considered important by the patient, rather than the complaint or diagnosis itself. This makes the goals of care patient-centred and it acknowledges the complementary nature of treatment modalities such as homeopathy and may be used to assess symptoms across a wide variety of complaints.

Aims

Aims of this audit were to use MYMOP2 to encourage medical staff to identify and record patients' most problematic symptoms, to facilitate goal setting, to assess outcome over time, to track utilisation of the package of care, and to test the internal consistency of the MYMOP2 profile score.

Methods

Recruitment ran from November 2005 to April 2006. Twenty patients for each of 10 doctors (i.e. 200 patients in total) in the BHH team were given a laminated letter inviting them to take part in the audit. All consecutive patients were included with the exception of two who refused to participate. As we merely observed routine practice no written consent was necessary. The doctor asked each patient to list her or his two most bothersome symptoms (sub-score 1 and 2) rated on a seven point numerical rating scale (0 = as good as it could be, 6 = as bad as it could be) as part of MYMOP2. If the patient was uncertain as to which symptom(s) to list, the doctor could help the patient by referring to what the patient had said during the consultation. MYMOP2 also identifies the patient's experience of the effect of her or his problem on a chosen (physical, social or mental) activity (sub-score 3) and general feeling of wellbeing (sub-score 4), both rated on a seven point numerical rating scale. The first consultation MYMOP2 form also asks patients to state how long they have had their most bothersome symptom. Patients are asked to rate the same symptoms at each consultation over the five visit package of care. MYMOP2 follow up form was completed at every subsequent visit attended. The main outcome measure was the MYMOP2 profile score comparing changes from the first to the last consultation for each individual patient. The profile score was the arithmetic mean of the reported sub-scores.

Assessing outcomes

The main analysis was an intention-to-treat analysis including both completers and non-completers and involved a paired-samples t-tests with a before to after treatment comparison as the difference in means for the main outcome measure (profile score) was found to be normally distributed (intra-individual differences were assessed using histograms and Fisher−Pearson standardized third moment coefficient = 0.060, normal range −0.281 to 0.281 for samples of 200). The median and interquartile range is presented for the MYMOP2 profile score and for all sub-scores as it is an ordinal rating scale and data therefore will be skewed. However, for the change in scores, the mean and standard deviation is presented if changes in scores are normally distributed, in

order to facilitate presentation of results and comparison with the main outcome measure. Moreover, repeated measures analysis of variance (ANOVA) tests were carried out using Bonferroni correction (corrected p-values are reported). Data for completers and non-completers were analysed separately. Completers are defined as patients who attended all five consultations and who responded to the MYMOP2 questionnaire after each consultation (although not necessarily responding to all four questions each time). Non-completers were any patient who did not complete the five visit package of care. SPSS (version 20) was used for statistical analyses.

We also carried out post hoc testing of the internal consistency of the MYMOP profile score using Cronbach's alpha (using no imputation for missing values). An ITT analysis using last observation carried forward (LOCF) was made and the monotone trend of data was assessed graphically to consider the appropriateness of using LOCF for replacing missing data.

Results

Identifying patient complaints

A total of 198 patients were included in the project with a range of long term diagnoses or complaints. Patients' main diagnoses were reported by their referring medical professional. Results are categorised according to ICD-10 (version 2010). For 76.3% of patients a single diagnosis was registered, whereas 20.2% suffered from two complaints and 3.5% from three. The most common category was neoplasms (16.7% of patients) where more than 6 out of 10 had been diagnosed with breast cancer. The second largest category was psychological complaints (13.9%), where two out of three patients suffered from anxiety or depression. This was closely followed by genitourinary problems (12.3%), including menopausal complaints (29% of these patients). Further details of patients' complaints can be found in Table 1. Most of patients' complaints were chronic, with 66.7% reporting a duration of more than one year (1−5 years: n = 53, 26.8%; more than 5 years: n = 79, 39.9%). Only 9 patients (4.5%) had their problems for less than 3 months and 41 patients (20.7%) had their problems for 3 months up to 1 year. Sixteen patients (8.1%) did not respond to this question.

Identifying problem symptoms

Baseline data

A wide range of symptoms measured using MYMOP2 were reported by patients, most commonly pain (70 patients, 35.4% of patients), mental symptoms (n = 59, 29.8%), tiredness/fatigue (n = 45, 22.7%), hot flushes/night sweats (n = 28, 14.1%), and various types of skin (n = 28, 14.1%), digestive (n = 22, 11.1%) and respiratory (n = 19, 9.6%) complaints.

Table 1 Patients' complaints reported by doctors, categorized according to ICD-10

Organ system or diagnostic category	*Number of complaints (%)*	*Most common complaints (number, percent of patients within diagnostic category)*
Neoplasms	42 (16.7%)	Breast cancer (27, 64.3%)
Mental & behavioral	35 (13.9%)	Anxiety & depression (31, 88.6%)
Genitourinary system	31 (12.3%)	Menopausal complaints (10, 32.3%)
Nervous system	29 (11.5%)	CFS (14, 48.3%), migraine (11, 37.9%)
Not classified elsewhere	25 (9.9%)	Fatigue/tiredness (7, 28.0%)
Skin & subcutaneous tissue	25 (9.9%)	Eczema (11, 44.0%)
Musculoskeletal & connective tissue	20 (7.9%)	Fibromyalgia (12, 60.0%)
Respiratory system	17 (6.8%)	
Digestive system	14 (5.6%)	
Circulatory system	9 (3.6%)	
Endocrine, nutritional & metabolic	2 (0.8%)	
Ear & mastoid process	1 (0.4%)	
Eye	1 (0.4%)	
Certain infectious & parasitic diseases	1 (0.4%)	

Patients may have more than one complaint and most complaints are also diagnoses.
Complaints are listed for diagnostic categories with min. 20 patients.

Table 2 Patients' baseline MYMOP2 scores (frequencies and percentage of completed data)

Score	*Symptom 1 Number, percent*	*Symptom 2 Number, percent*	*Activity Number, percent*	*Wellbeing Number, percent*	*Score range*	*Profile score Number, percent*
0	2 (1.0%)	0 (0.0%)	2 (1.1%)	10 (5.1%)	0 to <1	0 (0.0%)
1	5 (2.5%)	5 (2.9%)	0 (0.0%)	15 (7.6%)	1 to <2	3 (1.5%)
2	10 (5.1%)	9 (5.3%)	4 (2.2%)	32 (16.2%)	2 to <3	15 (7.6%)
3	19 (9.6%)	19 (11.1%)	24 (12.9%)	48 (24.4%)	3 to <4	53 (26.8%)
4	50 (25.3%)	44 (25.7%)	47 (25.3%)	46 (23.4%)	4 to <5	72 (36.4%)
5	63 (31.8%)	43 (25.1%)	44 (23.7%)	34 (17.3%)	5 to <6	52 (26.3%)
6	49 (24.7%)	51 (29.8%)	65 (34.9%)	12 (6.1%)	6	3 (1.5%)

Over eighty per cent of patients scored symptom 1 and 2, and limitation of activity, with 4, 5 or 6 points on the 0–6 point MYMOP2 numerical rating scale, and 2 to 5 points for the general feeling of wellbeing. The profile score was for 89.5% of patients in the range from 3 to less than 6 points. The median profile score was 4.25 (IQR 3.50–5.00). Further baseline data are presented in Tables 2 and 3.

Outcome over package of care

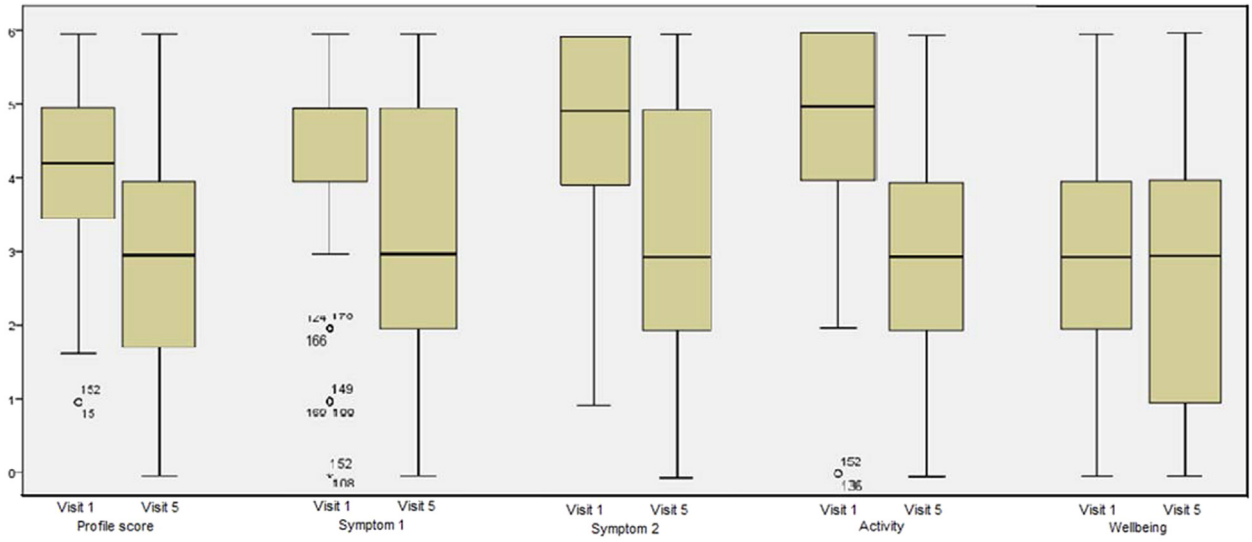
The intention-to-treat analysis showed that MYMOP2 mean profile scores improved on average by 1.24 points (95% CI 1.04, 1.44) ($p < 0.001$) from the first to the last consultation tested with a paired-samples t-test. The intention-to-treat analysis was carried out using last observation carried forward for replacement of missing data. Improvements in individual sub-scores were all found to be statistically significant ($p < 0.001$) (details in Figures 1 and 2). An analysis using Wilcoxon Signed Ranks Test carried out as a more conservative analysis also showed statistically significant changes for all sub-scores from the first to the last consultation ($p < 0.001$).

Repeated measures analysis of variance (ANOVA) tests were carried out using Bonferroni correction. About 30% of the variance could be explained by the time effect (Huynh-Feldt's test $p < 0.001$, partial eta squared 0.299). Pairwise comparisons showed that results for the profile score were statistically significant comparing the first visit to each of the follow-up consultations (all with $p < 0.001$). Repeated measures ANOVA tests (using Bonferroni corrections) carried out for each of the individual sub-scores at all five time points showed statistically significant results (all at $p < 0.001$). Mean profile scores and scores for each individual sub-score at each visit are illustrated in Figure 3. Analysis of results based on intra-individual

Table 3 MYMOP2 scores for completers at first and last consultation, and changes in scores

Score	*First consultation (median, IQR*)*	*Last consultation (median, IQR*)*	*Change (mean, 95% confidence interval)*	*P-value*
Profile score (n = 91) (main outcome)	4.25 (3.67–5.00)	2.50 (1.50–3.75)	1.63 (1.32–1.94)	<0.001
Symptom 1 (n = 91)	5.00 (4.00–6.00)	3.00 (1.00–4.00)	1.80 (1.36–2.24)	<0.001
Symptom 2 (n = 76)†	5.00 (4.00–6.00)	3.00 (2.00–4.00)	1.62 (1.17–2.06)	<0.001
Limitation in activity (n = 86)†	5.00 (4.00–6.00)	3.00 (1.00–4.00)	2.24 (1.83–2.66)	<0.001
General feeling of wellbeing (n = 91)	3.00 (2.00–5.00)	3.00 (1.00–4.00)	0.91 (0.51–1.32)	<0.001

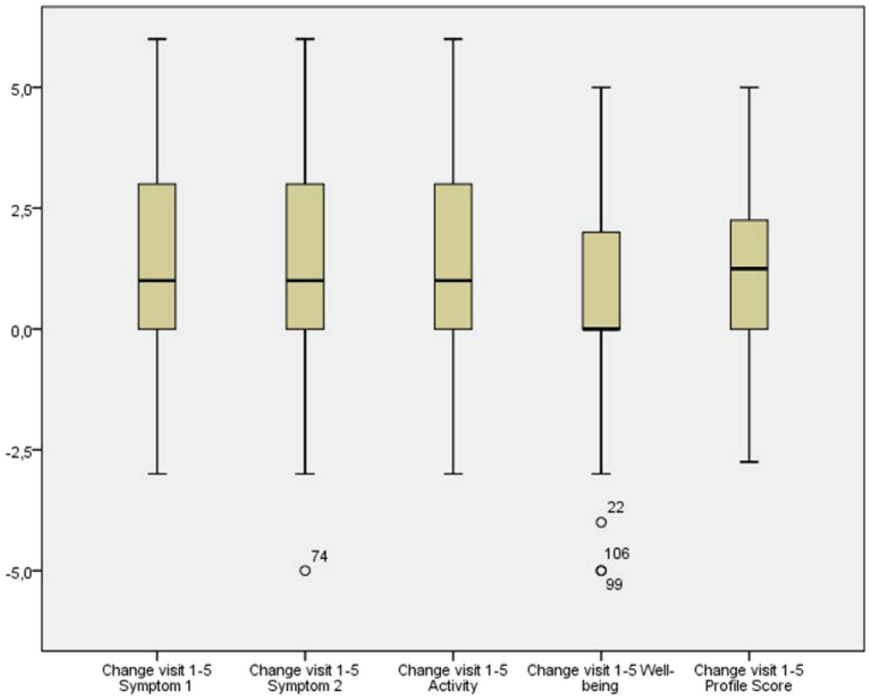
* Interquartile range (IQR): 25th and 75th percentile.
† Number of patients is below 91 as some did not complete all sub-scores.



Score	Visit 1 (median, IQR*)	Visit 5 (median, IQR*)	P-value
Profile score (n=198)	4.25 (3.50 – 5.00)	3.00 (1.75 – 4.00)	<0.001
Symptom 1 (n=198)	5.00 (4.00 – 5.25)	3.00 (2.00 – 5.00)	<0.001
Symptom 2 (n=171)	5.00 (4.00 – 6.00)	3.00 (2.00 – 5.00)	<0.001
Limitation in activity (n=185)	5.00 (4.00 – 6.00)	3.00 (2.00 – 4.00)	<0.001
General feeling of wellbeing (n=185)	3.00 (2.00 – 4.00)	3.00 (1.00 – 4.00)	<0.001

*Interquartile range (IQR): 25th and 75th percentile.

Figure 1 MYMOP2 scores at first and last visit (median, IQR).



Score	Change (mean, 95% CI)*	P-value
Profile score (n=198)	1.24 (1.04 – 1.44)	<0.001
Symptom 1 (n=198)	1.37 (1.10 – 1.65)	<0.001
Symptom 2 (n=171)	1.31 (1.02 – 1.60)	<0.001
Limitation in activity (n=185)	1.66 (1.38 – 1.93)	<0.001
General feeling of wellbeing (n=185)	0.70 (0.46 – 0.93)	<0.001

*CI: 95% Confidence Interval.

Figure 2 MYMOP2 changes from visit 1 to visit 5.

changes suggest that the main improvements took place from the first to the second consultation and the improvement was at least maintained. Similar results were found for completers (data not shown).

Outcome for patients completing package of care versus non-completers

A separate analysis of 91 patients who completed the entire package of care including five consultations was

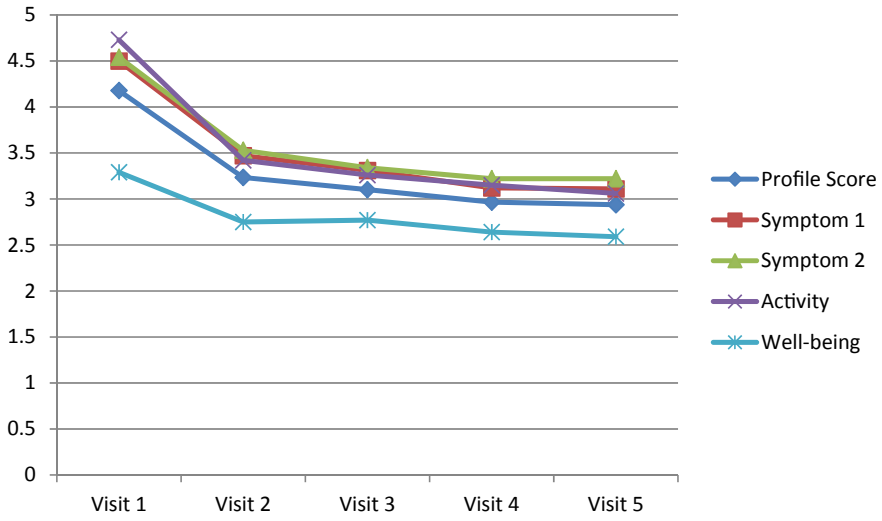


Figure 3 Mean MYMOP2 scores from visit to visit.

Table 4 MYMOP2 scores for non-completers at first and last consultation, and changes in scores

Score	*First consultation (median, IQR*)*	*Last consultation (median, IQR*)*	*Change (mean, 95% confidence interval)*	*P-value*
Profile score (n = 107) (main outcome)	4.25 (3.50–5.00)	3.25 (2.00–4.50)	0.92 (0.67–1.16)	<0.001
Symptom 1 (n = 107)	5.00 (4.00–5.00)	4.00 (2.00–5.00)	1.01 (0.67–1.35)	<0.001
Symptom 2 (n = 95)	5.00 (4.00–6.00)	3.00 (2.00–5.00)	1.06 (0.68–1.45)	<0.001
Limitation in activity (n = 100)	5.00 (4.00–6.00)	4.00 (2.00–5.00)	1.15 (0.80–1.50)	<0.001
General feeling of wellbeing (n = 106)	3.00 (2.00–4.00)	3.00 (2.00–4.00)	0.51 (0.25–0.77)	<0.001

* Interquartile range (IQR): 25th and 75th percentile.

also carried out. Improvements in patients' MYMOP2 scores were statistically significant for all sub-scores ($p < 0.001$) (Table 3). Improvements in MYMOP2 scores were more considerable when assessing results for completers only, compared to results for all patients.

The 107 patients who did not complete all five consultations included 18 (9.1% of all patients) who did not have any follow-up consultations, 45 (22.7%) who had one follow-up consultation, 18 (9.1%) who had two and 26 patients (13.1%) who had three follow-up consultations. For two (1.0%) patients data from the first consultation was missing. A paired-samples t-test using last observation carried forward showed that improvements in non-completers from the first to their last visit were statistically significant for the profile score and for all individual sub-scores ($p < 0.001$) (Table 4).

Profile scores from the first to the last consultation were significantly better for those patients who completed treatment (n = 91), compared to those who did not (n = 107) ($p < 0.001$), when using a general linear model controlling for baseline profile scores. Although both groups showed significant improvements, completers improved considerably more in symptom 1 ($p = 0.003$), symptom 2 ($p = 0.040$) and activity ($p < 0.001$), but not for general feeling of wellbeing ($p = 0.114$).

Repeated measures analysis of variance (ANOVA) tests with Bonferroni correction suggested results were significant at $p < 0.001$ for both completers and non-completers. About 35% and 27% of the variance can be explained by the time effect. Pairwise comparisons for the profile score were statistically significant comparing the first visit to each of the follow-up consultations (all with $p < 0.001$), but not for other comparisons (e.g. change from visit 2 to visit 3, or visit 2 to visit 4) ($p > 0.05$).

Internal consistency of MYMOP2 outcome measures

The internal consistency was tested in order to determine whether the profile score would be representative of the four individual MYMOP2 sub-scores. Scores for symptom 1 and 2, limitations in activity, and general feeling of wellbeing were tested for the change from first to last consultation and for each individual consultation. Statistical tests showed that the profile scores were overall representative (acceptable or good according to Kline 1999[13]) of the individual sub-scores when assessing changes from the first to last the consultation (Cronbach's alpha range 0.736–0.842), with the exception of scores at the first consultation which could be categorised as questionable (Cronbach alpha 0.651), and items were positively correlated to one another with one exception (symptom 1 and wellbeing at baseline). Based on the findings it was determined that the MYMOP2 Profile Score could be used with reasonably high confidence as the main outcome measure. The use of threshold levels when testing for internal consistency of outcomes should be treated with caution, in particular for outcomes where there are a higher number of individual items (around 10 or more). This was however not the case in our study, as MYMOP2 only has four sub-scores. We therefore feel more confident about our conclusions about the internal consistency of MYMOP2 and therefore the use of the Profile score as the main outcome.

Discussion

What is the clinical significance of the results?

Analyses of data collected through this audit suggest patients report improvements in their symptoms and these results are statistically significant both for those who complete and those who do not complete all five treatment sessions. The question arises whether the results are clinically significant. Guyatt et al.[9] have suggested the following threshold levels for clinical effects when using seven point numerical rating scales: >0.5 for a small effect, >1.0 for moderate effects, and >1.5 for large effects. These threshold levels were primarily intended for assessment of results in randomized controlled trials. The patients reported on in this audit did suffer from chronic long-term complaints, many of which can be considered to be incurable. It is therefore not unreasonable to assume that improvements at the threshold levels suggested by Guyatt et al. could be considered clinically significant. The degrees of change identified through the audit suggest a clinically significant or relevant improvement in patients' self-reported outcome scores that are at least moderate for changes in the profile score, symptom 1 and 2, large for limitations in activity and small (but still clinically significant) for general feeling of wellbeing.

Improvements were also clinically significant when assessing results for those who had all five treatment sessions, for the profile score and each individual sub-score. Improvements in the profile score, symptom 1 and 2, and limitation of activity were all large, and for general feeling of wellbeing at least small.

Improvements were less extensive for non-completers compared to completers, but were still clinically significant. They were close to moderate for the profile score, at least moderate for symptom 1 and 2, and limitations in activity, and small for general feeling of wellbeing (details in Table 4). The difference in improvement between completers and non-completers was small, but clinically significant for the profile score, symptom 1 and almost moderate for activity, whereas it was not clinically significant for symptom 2 and wellbeing.

Comparison with other studies

As with other data collection initiatives using various types of patient reported outcome measures[5,22,23,24,26,27,28] we have demonstrated clinical benefit as measured across a wide range of long term conditions. There have been other published data sets where MYMOP has been used to assess homeopathic treatment in NHS settings (e.g. Ref. 11). Bawden (2012)[2] using a slightly modified MYMOP, assessed 273 new patients over a five year period in an NHS clinic, finding patients were most commonly referred with mental health problems. Out of these, 75% demonstrated improvements in their symptoms and activity and 58% in their overall wellbeing.

The range of long term conditions seen in this project is comparable to national data collected previously from NHS settings[26] with breast cancer, anxiety, depression, chronic fatigue syndrome or eczema being common reasons for referral into the service. Numbers of women with breast cancer reflect regular referrals from surgical and oncological teams to the Integrative Cancer Care Service where we offer symptom control for patients with side effects of their cancer treatments. MYMOP2 demonstrated significant symptom burden for patients in the majority of cases rating their symptoms as greater than 4 on the 0 to 6 point scale. MYMOP2 was completed easily by patients and provided a clear record.

Reasons for non-completion

One hundred and seven patients did not complete the package of care, five patients died from cancer. The reasons for discontinuation of attendance for the remaining 104 patients are unclear. It is likely that some patients discontinued treatment due to lack of improvement in their symptoms. However, the 4 follow-ups is a guide and not every patient will require the full 4 follow-up consultations to return their health to a level they are happy with. By using MYMOP2 in this cohort of patients we have been able to see improvements after one or two follow-up consultations. This may have led to the patient not wanting or needing to take time to return to complete a package of care. This was found by Endrizzi & Rossi (2006)[6] who carried out a telephone survey to determine why 56.5% of a cohort of patients attending an outpatient service in Italy did not return for follow-up consultations. Seventy three (70.2%) out of 104 eligible patients were contacted and over half of those patients referred to effectiveness of the treatment as the reason they did not return. Improvements in our study were found in both completers and in non-completers, although they were more significant for the patient group that stayed in the system. It is not clear if completers improved more than non-completers because they continued treatment, or whether they continued treatment because they experienced greater improvements. Maximising clinic utilisation is an important part of running a cost-effective service. Understanding how patients would ideally use the service, e.g. only attending with perceived need, could be an important design feature in the future. Mullen (1997)[14] concluded that treating patients as a decision maker is a fundamental step towards compliance and a recent report by the King's Fund[15] described patient empowerment as an untapped resource within the NHS.

Wellbeing

We found a contrast between the level of wellbeing reported by patients and the effect of their symptoms on everyday life as represented by their limitation of activity score. The percentage of patients reporting a baseline adverse activity score of 4−6 was 83.9%. The percentage reporting a similarly adverse effect on general wellbeing was 65.1%. At the other end of the scale, 28.9% reported that their wellbeing was reasonably well maintained (score 0−2), while only 3.3% were able to maintain their activity to that level. Starting from that relatively good baseline, the wellbeing scores for both completers and non-completers improved proportionately less than their symptom and profile scores but remained better overall. Completers' mean final activity score almost reached equivalence with their mean wellbeing score. The concept of wellbeing is vague. By contrast with 'health', which is generally regarded as having objective criteria to do with bodily and mental structure and function and the absence of disease states, 'wellbeing' is subjective and has many dimensions including physical, emotional, intellectual, spiritual, social and environmental condition and circumstances. Brown and Alcoe (2010)[3] suggest wellbeing is essentially about how we relate inwards to ourselves and come to understand ourselves through four dimensions: physical, mental, emotional and spiritual; and may be a more static phenomenon than symptoms associated with a chronic complaint. We would like to investigate this further.

Limitations

This study was designed as an audit rather than research but having collected an interesting data set we wanted to report the outcomes for a relatively large cohort of patients. It is well-known that there is a high risk of bias in uncontrolled studies, including risk of selection bias, performance bias and reporting bias. There is also risk of attrition bias which we in have tried to account for by applying a last observation carried forward strategy for missing data and by comparing differences between completers and non-completers.

The last observation carried forward is an appropriate and a conservative approach as a monotone trend of the data was found (data not shown). The test showed trends

in the development of patients' health to be reasonably similar (when comparing groups of 20 patients). In order to consider a more conservative assessment of results we also carried out significance tests using Wilcoxon Signed Ranks Test, but found these also to be statistically significant for all outcomes ($p < 0.001$).

There was no pre-published protocol for this project, but we have as much as possible followed the STROBE statement checklist to report on all items that should be included in observational studies (available at e.g. http://www.plosmedicine.org). The reader should be cautious about drawing any conclusions as to whether the improvements seen for patients were due to the homeopathic intervention, specific effects of homeopathic medicines, non-specific effects of the whole encounter, regression to the mean effects or placebo effects. However it is not always appropriate to use randomised controlled trial design in routine clinical practice. The fact that most patients have had their complaints for many years and then demonstrated improvements is notable and adds to the emerging body of observational data that suggests when an individual embarks on homeopathic care many will experience improvements in symptoms and wellbeing (e.g. Refs. 1,7,8,21,25,26).

In terms of wellbeing interesting questions arise. An integrative medicine approach which supports individuals with a range of complementary and conventional approaches, some that support symptom control and others that support a change in orientation towards perceived wellness, may have an additive and positive effect when combined. Supporting clients to choose approaches that inspire their own self care programme could improve health, wellbeing and happiness over time. One study from Bristol evaluated a social prescribing holistic project at a GP practice with a Healthy Living Centre Wellbeing Programme for clients with mental health problems. This centre has adopted a holistic and preventive approach to health needs and seeks to work with beneficiaries with long-term conditions and to support them to play a central role in managing their own care. Using a social return on investment model of evaluation there were improvements in depression, anxiety and social isolation over the study period. Analysis of GP contact times also suggest that for 60% of beneficiaries there is a reduction in their GP attendance rates in the 12 months post intervention compared to the 12 months period prior to referral.[12]

We plan to carry out an analysis of previously published studies using MYMOP to assess the development of patient-reported outcomes. We are also in the process of designing more rigorous ways to monitor outcomes in large cohorts of patients and are exploring a social return on investment economic model to capture outcomes in a holistic and rigorous way that can then inform research and quality assurance programmes in the future.

Our findings reflect other data sets that demonstrate clinical benefit over a wide range of complaints for homeopathic interventions. Acknowledging limitations in interpretation of findings, the results of our MYMOP2 analysis can be communicated to commissioning teams and health care providers to provide information on the range of clinical complaints and potential benefits as demonstrated using MYMOP2 to assess routine homeopathic clinical practice. Including non-pharmaceutical approaches such as homeopathy within a social prescribing model is an important way to increase patient choice and support self-care which is a crucial part of creating sustainable health care in the future.

Conclusions

MYMOP2 is a practical outcome measure in routine clinical practice for long term conditions. It has the potential to encourage medical staff to identify and record troublesome symptoms in order to communicate outcomes of homeopathic treatment to referring colleagues. Whilst it may not be feasible to undertake MYMOP2 data collection in day to day routine practice and analyse results, the principles of goal setting around troublesome symptoms and wellbeing can be used in clinical practice. MYMOP2 demonstrated significant symptom burden across a range of complaints that improved over the course of a package of care with clinically relevant changes, in particular for patients staying in the system. An intention-to-treat analysis showed statistically significant improvements in patients' self-reported MYMOP2 scores from the first to the last visit. Improvements were considered to be clinically significant and at least moderate, using Guyatt et al.'s (1998)[9] suggested threshold levels. This interpretation must however be treated with caution as these threshold levels are normally used for RCTs.

Competing interests

The authors declare they have no competing financial interests.

Authors contributions and acknowledgements

ET and SB designed and conducted the audit. PV analysed data and authored sections of the text. All authors reviewed and made changes to the final text. Our thanks to all patients who took part and the staff who helped administer the audit, to Dr Jeremy Swayne who helped to write the paragraphs relating to wellbeing, to Dr Robert Mathie for advice, as well as to Dr Andreas Gleiss, Dr Mark Strong and Dr Mahitha Gummadi for advice on statistical analyses.

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