

Electronic Registration in Complementary/ Homeopathic Medical Practice with Identification of ‘Best Homeopathic Cases’: A Pilot Study

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Homeopathy

Abstract

Background Practice-based registration could identify ‘general’ and ‘homeopathic’ prognostic factors for therapeutic success in patients who seek complementary and alternative medicine (CAM)/homeopathic treatment. Identification of ‘best homeopathic cases’ within a database could inform clinical research and improve homeopathic practice.

Objective To investigate the feasibility of registration in daily CAM/homeopathic practice, evaluate patient-reported outcome measures and tools for identifying ‘best homeopathic cases’ and to make recommendations for an electronic database.

Methods In 2015 and 2016, 25 homeopathic doctors registered details of a maximum of 20 patients each, with 6 months of follow-up (extended follow-up for ‘best homeopathic cases’), in Excel or in the Homeopathic Administration and Registration Program (HARP) database. Informed consent was obtained from each patient. Patient-perceived change of main complaint was measured by a 7-point Likert scale. Best homeopathic cases were defined by treatment with one homeopathic medicine, ≥ 2 months of follow-up, result score +2 to +4 on a 9-point Likert scale by the doctor, and by changes that could be attributed to the homeopathic medicine. Association between scores for change of main complaint and scores for ‘best homeopathic case’ was analysed by the Kruskal gamma test.

Results Three-hundred and ninety-nine patients were included. In 49.1%, the main complaint was present for ≥ 2 years. The most common diagnosis was ‘fatigue’ ($N = 56$; 14%). Major improvement in the main complaint (score +3) was reported by 22 to 26% at consecutive follow-up visits. One-hundred and ninety-six patients were treated with a single homeopathic medicine, among whom 66 ‘best homeopathic cases’ were identified. The correlation between patient-reported changes of main complaint and assessment by the doctor was significant ($\text{gamma} = 0.832$; $p < 0.001$).

Conclusions Registration of (co-)diagnoses, chronicity, treatments and outcomes in homeopathic practice with identification of ‘best homeopathic cases’ is feasible, using the tools provided. A user-friendly electronic database for efficient recording is recommended.

Keywords

- ▶ complementary medicine
- ▶ homeopathy
- ▶ ‘best homeopathic cases’
- ▶ data collection
- ▶ prognostic factors

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Introduction

Treatment by a homeopathic practitioner as an addition to conventional care can have positive health effects on patients with chronic illness. This was reported in various observational studies with (additional) homeopathic treatment in Germany, Switzerland, the United Kingdom and Italy.¹⁻⁶ It is essential to identify prognostic factors of therapeutic success, to give tailored advice for patients consulting a homeopathic practitioner. In these studies, positive changes were observed in children with asthma, eczema or recurrent infections, and in adults with irritable bowel syndrome, allergic rhinitis, anxiety, depression, chronic fatigue syndrome, headache, cough and other respiratory complaints, as well as in women with menopausal problems. In one study with reported long-lasting decrease in disease severity (8 years), younger age, female gender, more severe disease at baseline and multiple infections were 'general' prognostic factors of better therapeutic success.³

Personalised Medicine

In homeopathic treatment, 'homeopathic' prognostic factors should be identified, in addition to 'general' prognostic factors. Individualised homeopathic medicine prescription is not only based on a medical condition, but also on other factors: it is 'personalised medicine'. This means that '...in addition to the regular examination of the patient... a diagnostic test is performed to assess certain patient characteristics as a basis for the choice of therapy and/or therapy control'.⁷ In general medicine, 'personalised medicine' mostly refers to genetic or microbiological traits; in homeopathy it often refers to observed personal symptoms/characteristics. 'Keynote symptoms' are specific personal symptoms/characteristics that strongly indicate the choice for a particular homeopathic medicine.⁸ Thus, they can be considered as potentially 'homeopathic' prognostic factors of therapeutic success, associated with a specific homeopathic medicine.

A great deal of practical knowledge about homeopathic keynote symptoms is hidden in patient files of homeopathic practitioners. These treasures should be unearthed. Systematic collection and analysis of relevant clinical data obtained by doctors in routine practice can form a base for targeted research in homeopathy, as was stated by Mathie and Robinson in 2006.⁶ Identifying 'general' and 'homeopathic' prognostic factors is essential for improving individualised homeopathic approaches for all patients, including those with chronic disease.

Background

In 2015 to 2016, a pilot study was conducted about electronic registration in complementary and alternative medicine (CAM) practices specialised in homeopathy, in The Netherlands. This was organised in anticipation of the development of an electronic registration/administration programme. One of the requirements of such a system would be to facilitate practice-based research. Previous studies in the United Kingdom already demonstrated that it was feasible to register data about patients, diagnosis, treatment and out-

comes in daily homeopathic practice.⁶ In our study, additional questions were added, such as reasons why patients consulted a homeopathic practitioner, chronicity of main complaint, co-diagnoses and patient-perceived changes of main complaint. Another object was prospectively to evaluate the feasibility of identifying 'best homeopathic cases' within an electronic database. If, in an individual patient, a considerable improvement in health was observed and this improvement could be attributed to treatment with one particular homeopathic medicine, the case would be labelled 'best homeopathic case'. The causal relationship between improvement and the homeopathic medicine could be corroborated with the modified Naranjo algorithm (see section 'Methods'). 'Best homeopathic cases' could be further explored to identify specific potential prognostic factors,

Objectives

The objectives of this study were:

1. To investigate the feasibility of data registration in CAM practices in The Netherlands, with identification of 'best homeopathic cases' within a database.
2. To evaluate reasons why patients seek CAM treatment, the chronicity of main complaint, number/percentage of patients with chronic complaints, prevalence of diagnosis categories, most frequently reported diagnoses, number/percentage of persons with co-diagnoses, types of treatment as offered by the doctors, use of and outcomes for patient-reported outcome measures (PROMs).
3. To make recommendations for future electronic data registration in daily practice.

Methods

Study Design

The study was a prospective multi-centre observational cohort study. In ► **Fig. 1**, the project is summarised.

Procedures

All participating doctors were members of the Dutch Association for Integrative Medicine (AVIG), section of homeopathy. All practiced complementary medicine in private practice and had specialised in homeopathy (henceforth, in this paper, termed CAM/homeopathy). During a workshop before the start of the project, the doctors received instructions from the study coordinator and practised the entering of data. They also received written instructions.

Participating homeopathic doctors would each register details of a maximum of 20 consecutive patients who visited for the first time or had not been visiting for the past 2 years and presented with a new complaint. Patients received written information about the study. Oral consent to use the anonymised data for observational investigation was requested from each patient and approval or denial was recorded in the patient file. All consenting patients were given a study code, consisting of a physician code and a number code in rank order of inclusion. The period of entering new patients was restricted to 6 months. Follow-up visits of all included patients

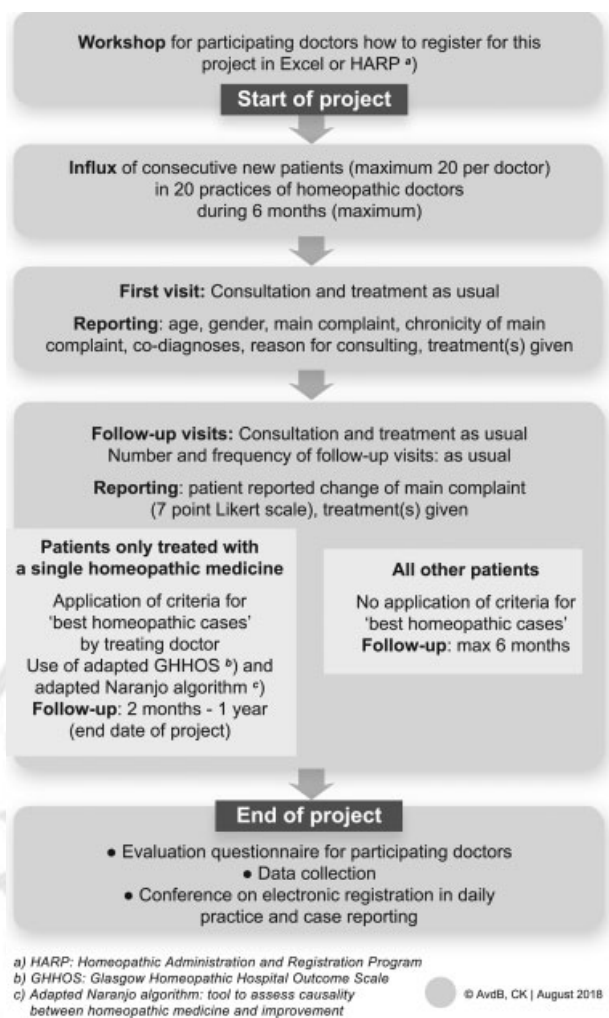


Fig. 1 Project design.

were recorded during 6 months for each patient. During the study period, the study team decided to extend the follow-up duration for 'best homeopathic cases' until the end-date of the study, to be able to include more 'best homeopathic cases'.

All participating doctors provided treatments 'as usual'. They did not receive any advice; nor was there any restriction on treatment type, potency, dose of homeopathic medication, follow-up frequency, referral or any other part of the treatment.

Data Collection

Data were registered in a specially prepared spreadsheet (Excel) or in a database, the Homeopathic Administration and Registration Program (HARP). HARP was designed in the programme FileMaker for homeopathic practice. It contained several partitions that could be used separately or in combination: registration of patient characteristics, medical diagnosis, homeopathic medicines and effects; agenda; financial administration and correspondence. It was used by 20 to 25 homeopathic doctors in The Netherlands, sometimes as a full electronic patient file, mostly in combination with paper-based patient files.

For most items, drop-down menus facilitated the entering of data. The study started at the end of March 2015 and terminated on 1 November 2016. All participating doctors were asked to send their data to the study coordinator at the end of the study period.

Characteristics and Measurements

At the first visit, the treating doctor entered the following data: date of visit, age at first visit, reason for wanting complementary/homeopathic treatment, diagnosis of main complaint, duration of main complaint, co-diagnoses (maximum of 3) and advice or treatment(s) given at the end of the visit.

At every follow-up visit, the patient was asked to assess the change of main complaint in relation to the first visit. This score would be entered into the system by the doctor. The doctor was also asked to record treatments given, aggravations, and to give a score for 'best homeopathic case' if appropriate. At all visits, there was an opportunity to make remarks, such as the nature of any aggravations or reasons for terminating treatment.

- Reasons for CAM/homeopathy were recorded in five categories, in codes.
- Main diagnosis and co-diagnosis were defined by the International Classification for Primary Care (ICPC-2).⁹
- Duration of main complaint was reported in eight categories, in codes.
- Type of treatment was recorded (up to a maximum of 4) as follows: Homeopathic treatments were coded by the name of the homeopathic medicine. A list of 3,785 homeopathic medicines, including official botanical names for the plant medicines, was provided. This was a drop-down list in the database programme HARP and a copy-paste list in the spreadsheet. Other treatment types were coded in categories, by numbers. They included, for example, dietary interventions, supplements, acupuncture, bio-information therapy, naturopathy, neural therapy and complex homeopathy. If, at follow-up visits, a treatment was started for a new diagnosis, the code for the new diagnosis was entered.
- Patient-perceived change of main complaint was measured by a 7-point Likert scale, ranging -3 through +3. The patient would be asked: 'Have your symptoms improved, deteriorated or remained the same?' The following question would be: 'Was it a major (+3/-3), moderate (+2/-2) or minor (+1/-1) improvement/deterioration?'. This scale was chosen because it had been previously used and found useful in observational studies in homeopathic practice.^{2,6}

'Chronic' was defined by a duration of ≥ 3 months. In a medical context, this period of time is mostly associated with 'chronic'.^{10,11}

'Best Homeopathic Cases'

The set of criteria that was used to define 'best homeopathic cases' is presented in ►Table 1. The doctors would apply these criteria in patients whose symptoms improved after

Table 1 Criteria to define 'best homeopathic cases'

Criteria to define 'best homeopathic cases' by the treating doctor All criteria must be present
1. Score +2, +3 or +4 by the adapted GHHOS ^a
2. One single homeopathic medicine, no other treatment
3. Follow-up of 2 months or more (in chronic cases)
4. Causality between treatment and result must be plausible; use of adapted Naranjo algorithm is advised

^aThe adapted Glasgow Homeopathic Hospital Outcome Scale (GHHOS) is a 9-point Likert scale. It was adapted by the Committee for Methods and Validation of the (previous) Dutch Homeopathic Doctors Association (VHAN).

In chronic cases: +4 = complete recovery; +3 = main complaint (almost) disappeared and major improvement of general well-being; +2 = major improvement in main complaint and improvement in general well-being.

In acute cases, without long-term effects: +4 = recovery was quicker than expected, considering natural courses, pre-existing illness (totality and severity); without complications, without residual symptoms, clinical parameters improved (if applicable) AND the case belongs to the best 10% of homeopathic cases as estimated by the treating doctor; +2 = recovery was quicker than expected (see above) AND the case does NOT belong to the best 10%, but it does belong to the best 50% of homeopathic cases as estimated by the treating doctor; +3 is not applied in acute cases.

In acute situation with long-term effects: see chronic situation.

they had received an individually prescribed homeopathic medicine as the only treatment. The timing when to define a 'best homeopathic case' could vary. It would depend on the time (≥ 2 months) when moderate or major improvement would be achieved. A 9-point Likert scale originally ranging from -4 to $+4$ was used by the doctors to assess treatments results: score $+2/+3/+4$ meant moderate-to-major improvement/cure of main complaint and general health (see also ►Table 1). The scale was an adaptation of the Glasgow Homeopathic Hospital Outcome Scale (GHHOS). It had been previously used in a practice-based research project in The Netherlands.¹² It was already incorporated in HARP and many participating doctors had worked with it before. If an outcome score was entered for 'best homeopathic case', the patient record would thus be identified as 'best homeopathic case' in the database.

A modified version of the Naranjo algorithm was offered to assist in the assessment of the causal association between treatment and result, see ►Table 2. The Naranjo algorithm was originally developed to assess the causal relationship between adverse effects and medicines.¹³ It has been modified to assess the causal relationship between beneficial effects and homeopathic medicines and is in the process of validation. A more recent version of the modified Naranjo algorithm was published as an appendix to the HOM-CASE CARE checklist, an extension of the general checklist for CASE RReports (CARE).^{14,15}

The participating doctors evaluated the usefulness of the PROMs as well as the criteria for 'best homeopathic case' by completing an online questionnaire at the end of the study.

Analysis

Descriptive analysis was used to describe patient characteristics, diagnoses, co-diagnoses, chronicity of main complaint, number of patients with a chronic main complaint, reasons why patients sought complementary treatment/homeopathy, types of treatments offered, number of follow-up visits, outcomes of PROMs, opinion of the participating doctors

about PROMs, number and characteristics of identified 'best homeopathic cases'.

At each visit, the number and percentage of patients within the seven categories of the Likert scale for change of main complaint ($-1, -2, -3, 0, +1, +2, +3$) were calculated. Qualitative and descriptive analysis was used to analyse the outcomes of the questionnaire that was sent to the participating doctors about experiences with and opinion about PROMs, adapted GHHOS and the modified Naranjo algorithm.

The outcome statistics refer only to patients who were reassessed at follow-up. The correlation between the patient's perceived change of main complaint and the doctor's assessment by the GHHOS was analysed. Complete pairs of scores of GHHOS/Likert scale (recorded at the same time point) were identified (intention to treat analysis, last paired observation carried forward). Associations were analysed by the Kruskal gamma test for non-Normally distributed data.¹⁶

Results

Initially, 38 doctors expressed interest in participating. Of them, 26 attended the workshop, 25 sent in final data (5 registered in HARP, 20 in Excel) and 20 completed the questionnaire for doctors. At the first visit, 399 patients were included. In ►Table 3, characteristics are presented for all patients ($N = 399$) as well as for the sub-group 'best homeopathic cases' ($N = 66$).

All Patients

In the total study sample, the most reported main diagnosis was fatigue ($N = 56$; 14%). Other frequently reported diagnoses were sleep disorders ($N = 17$; 4.3%), eczema ($N = 30$; 7.5%), hyperactive child ($N = 11$; 2.8%) and menopausal complaints ($N = 11$; 2.8%).

Reasons to consult a CAM/homeopathic practitioner were 'insufficient result with conventional treatment' (43.9%), 'first choice, preference for natural approach' (36.3%), 'no conventional treatment available' (11.5%) or 'side-effects of conventional treatment' (5.3%)—see also ►Table 3. A chronic

Table 2 Adapted Naranjo algorithm^a, a tool to assess a causal relation between homeopathic medicine and improvement

Questions/items to check	Yes	No	Not sure or not applicable
1. Was there an improvement in the main symptom or condition for which the homeopathic medicine was prescribed?	+1	-1	0
2. Did the clinical improvement occur within a plausible timeframe relative to the drug intake?	+1	-2	0
3. Was there an initial aggravation of symptoms?	+1	0	0
4. Did the effect encompass more than the main symptom or condition: i.e., were other symptoms ultimately improved or changed?	+1	0	0
5. Did overall well-being improve?	+1	0	0
6. Did the course of improvement follow Hering's Rule?	+2	0	0
7. Did 'old symptoms' (defined as non-seasonal and non-cyclical symptoms that were previously thought to have resolved) reappear temporarily during the course of improvement?	+1	0	0
8. Are there alternate causes (other than the medicine) that solely could have caused the improvement? (Consider known course of disease, other forms of treatment, and other clinically relevant interventions)	-3	+1	0
9. Was the effect confirmed by objective evidence as measured by external observation(s)?	+2	0	0
10. Did repeat dosing, if conducted, create similar clinical improvement?	+1	0	0
Instructions: Answer questions 1–10 and add the scores. Outcome: A total score of ≥ 5 seems an indication for a positive causal relation. Additionally, you could intuitively think: 'This is the kind of case to tell to a sceptic colleague.'			

^aThe Adapted Naranjo algorithm is a clinical outcome assessment tool in development. For the project, version June 2014 was used (with small adaptations), by the Clinical Data Working Group of the Homeopathic Pharmacopoeia of the United States, while in development for the Homeopathic Pharmacopoeia Convention of the United States (HPCUS), available online at HPUS.com.

main complaint (≥ 3 months) was reported in 335 patients (83.9%).

At the first visit, individually selected homeopathic medicines were prescribed in 364 out of 399 patients (91.2%). In 168 patients (42.1%), this was combined with other treatments, such as vitamins/supplements (13.0%), diet/nutrition (10.0%), bio-information therapy (7.0%), complex homeopathic medicines (4.5%), lifestyle interventions (3.8%), probiotics (3.0%) and other therapies (4.9%) (more than one other treatment per patient possible).

A second visit was recorded in 86% of the patients, a third in 58.6%, a fourth in 34.3%, a fifth in 21.3%, and more than five in 12.6%. The intervals between visits varied from 5.9 to 8.9 weeks. Sometimes the doctors reported reasons why a patient discontinued treatment (e.g. it went well, there was no improvement, financial reasons, inter-current disease), but more often we just did not know.

Scores associated with moderate-to-major improvement (+2/+3 on a 7-point Likert scale) were reported in 130 patients (38%) at the second visit (26 missing values [7.6%]; $N = 343$), in 103 patients (44%) at the third visit (21 missing values [9%]; $N = 234$), and in 56 patients (41%) at the fourth visit (16 missing values [11.7%]; $N = 137$).

The follow-up time for assessment by PROMs varied between 1 and 6 months after the first visit for most patients and up to 1 year for cases labelled as 'best homeopathic cases'. The five most frequently reported diagnoses with patient-perceived moderate-to-major improvement change

of main complaint (+2/+3) were fatigue, eczema, sleep disorders, hyperactivity in children and menopausal complaints (see ►Table 4).

Tools to Identify 'Best Homeopathic Cases'

In 196 patients who were treated with a single homeopathic medicine and no other treatment, 75 'best homeopathic cases' were identified by the doctors. After applying inclusion criteria by the investigators (excluding patients with more than one treatment, or follow-up < 2 months in chronic complaints), 66 patients were found eligible (33.7% out of 196). In 20 doctors, 3 (15%) found it was always easy to decide if they could label a case as 'best homeopathic case' and rate an adapted GHOS-scale, 12 doctors found it was sometimes difficult (60%), 2 found it was always difficult (10%), while 3 did not know (15%). The modified Naranjo algorithm was used by 8 doctors (40%); 7 thought it was a good tool for the assessment of 'best homeopathic cases' and 1 thought it was not.

Outcomes of 'Best Homeopathic Cases'

Within the group 'best homeopathic cases' ($N = 66$), the most frequent diagnosis was fatigue ($N = 11$; 16.7%). Other reported diagnoses with $N > 1$ were eczema, sleep disorders ($N = 3$; 4.5%), stomach pain, migraine, anxious/nervous/tense feeling, feeling down/depressed, hyperactive child, anxiety/fear, difficult breathing, other infections such as respiratory tract infections, allergic rhinitis, cystitis/

Table 3 Characteristics of all included patients and of the sub-group 'best homeopathic cases'

	All patients (N = 399)	Best homeopathic cases (N = 66)
Gender, N (%)		
Male	136 (34.1%)	23 (34.8%)
Female	263 (65.9%)	43 (65.2%)
Age (means in years)	43	37
Age categories, N (%)		
0–9 years	73 (18.3%)	8 (12.1%)
10–19 years	40 (10.0%)	12 (18.2%)
20–29 years	34 (8.5%)	3 (4.5%)
30–39 years	49 (12.3%)	9 (13.6%)
40–49 years	57 (14.3%)	9 (13.6%)
50–59 years	74 (18.5%)	10 (15.2%)
60–69 years	15 (12.8%)	11 (16.7%)
70–79 years	13 (3.3%)	2 (3.0%)
80–89 years	7 (1.8%)	2 (3.0%)
90–99 years	1 (0.3%)	0 (0.0%)
Reason for CAM/homeopathy, N (%)		
First choice, preference for natural approach	145 (36.3%)	19 (28.8%)
Insufficient effect of conventional treatment	175 (43.9%)	32 (48.5%)
No conventional treatment available	46 (11.5%)	11 (16.7%)
Side-effects of conventional treatment	21 (5.3%)	3 (4.5%)
No specific reason; none of the above	8 (2.0%)	1 (1.5%)
Missing values	4 (1.0%)	0 (0.0%)
Duration of main complaint, N (%)		
< 1 week	1 (0.3%)	0 (0.0%)
1 week–1 month	8 (2.0%)	1 (1.5%)
1–3 months	34 (8.5%)	4 (6.1%)
3–6 months	42 (10.5%)	11 (16.7%)
6 months–1 year	40 (10.0%)	6 (9.1%)
1–2 years	57 (14.3%)	4 (6.1%)
2–5 years	65 (16.3%)	12 (18.2%)
> 5 years	131 (32.8%)	25 (37.9%)
Missing values	21 (5.3%)	3 (4.5%)
Most reported main diagnosis, N (%) ^a		
General	72 (18.0%)	11 (16.7%)
Gastrointestinal tract	33 (8.3%)	6 (9.1%)

Table 3 (Continued)

	All patients (N = 399)	Best homeopathic cases (N = 66)
Joints, muscles	23 (5.8%)	0 (0.0%)
Neurological	20 (5.0%)	5 (7.6%)
Psychological	75 (18.8%)	14 (21.2%)
Respiratory tract	51 (12.8%)	11 (16.7%)
Skin	70 (17.5%)	9 (13.6%)
Female genitals	16 (4.0%)	2 (3.0%)
Number (max.: 3) of reported co-diagnoses, N (%) ^a		
At least one	280 (70.2%)	46 (69.7%)
At least two	142 (35.6%)	23 (34.8%)
At least three	64 (16.0%)	7 (10.6%)

^aCoded by the International Classification for Primary Care (ICPC), version 2.

infections of urinary tract, and menopausal complaints (each: N = 2; 3%). A high percentage of 'best homeopathic cases' (N = 61; 87.5%) was associated with chronic main complaints (≥ 3 months); 62.2% had suffered for ≥ 1 year and 56.1% had suffered for ≥ 2 years. In 46 patients (69.7%), at least one co-diagnosis was reported. When a joint/muscle complaint was the main diagnosis, no cases were labelled as 'best homeopathic case' (see ► **Table 3**).

Homeopathic medicines used in 'best' cases with N > 1 were *Natrum muriaticum* (N = 9); *Causticum*, *Mercurius vivus*, *Phosphorus*, *Ignatia amara* (N = 3); *Arnica montana*, *Carcinosinum*, *Stramonium*, *Lycopodium clavatum*, *Magnesium muriaticum*, *Natrium phosphoricum* and *Sulphur* (N = 2).

Association between Adapted GHHOS and PROMs

Fifty-five complete paired scores of adapted GHHOS for 'best homeopathic cases' and Likert scale for change of main complaint were identified. A strong and significant association was found (gamma = 0.832; standard error 1.09; 95% confidence interval, 0.62 to 1.00; p < 0.001).

Evaluation by Doctors

Evaluation questionnaires were completed by 20 doctors, of whom 19 (95%) had appreciated having participated in the project. Several of them quoted: '...though it took more time than expected'; 'it takes discipline to enter the data after every visit and that was not always easy'; 'I appreciated the feed-back about my own practice'. They reported two main obstacles. First, the extensive drop-down list with homeopathic medicines using official botanical nomenclature formed an obstacle. It differed from the names they were used to (e.g. *Anemone pulsatilla* instead of *Pulsatilla pratensis*). Second, users of HARP complained about software updates during the study time and subsequent changes.

The participating doctors evaluated as 'useful' the Likert scale for change of main complaints.

Table 4 Top five diagnoses in all patients, with number and percentage of patients who reported moderate-to-major improvement of main complaints at follow-up (other scores and missing values not shown)

All patients (N = 399)	Score: +3 N (%) ^a	Score: +2 N (%) ^a	Scores +3/+2 summarised N (%) ^a	Total number of patients with this diagnosis
Fatigue	13 (23.2%)	10 (17.9%)	23 (41.1%)	56
Eczema	9 (30.0%)	4 (13.3%)	13 (43.3%)	30
Sleep disturbance	4 (23.5%)	2 (11.8%)	6 (35.3%)	17
Hyperactive child	4 (36.4%)	1 (9.1%)	5 (45.5%)	11
Menopausal complaints	5 (45.5%)	1 (9.1%)	6 (54.5%)	11

^aPercentage of patients with this diagnosis.

+2: Patient reported moderate improvement of main complaint compared with the first visit.

+3: Patient reported major improvement of main complaint (or cure) compared with the first visit.

Discussion

It proved feasible to register the characteristics, the diagnosis, the treatment and the results of 399 patients in practices of 20 doctors specialised in CAM/homeopathy in The Netherlands, and to identify 66 'best homeopathic cases'. 60.7% (summed up) of all patients had turned to CAM/homeopathy because conventional care had been ineffective, unavailable or caused side-effects (reasons summarised in ►Table 3). In 85% of all patients, the main complaint was chronic (≥ 3 months), in 32.8% even ≥ 5 years, while in 70% at least one co-diagnosis was recorded (see ►Table 3). Our outcomes confirm other findings: patients in CAM practices often present with chronic, 'general' complaints, especially 'fatigue'.¹⁷ Positive outcomes by PROMs (38–44% for summarised scores of +2 and +3) are lower than in other observational studies on homeopathy with similar 7-point Likert scales. Spence et al reported improvement scores +2/+3 in 50.3%, while Mathie and Robinson reported improvement scores +2/+3 in 58.9% in all patients and 48.5% in patients with chronic disease.^{2,6} The relatively large percentages of missing values (included in the total numbers) in our study could partly explain these differences. It goes beyond the scope of this article to further analyse and compare other factors that could influence outcomes by PROMs, such as setting, reimbursement, population characteristics, disease characteristics, chronicity of complaint, co-morbidity, treatments given, follow-up duration or method of reporting.

Complementary and Alternative Medicine/ Homeopathy in Health Care

In The Netherlands, between 2010 and 2012, 6% of the population consulted an alternative practitioner in the previous year, according to Statistics Netherlands (Centraal Bureau voor de Statistiek, CBS).¹⁸ An independent researcher of the Dutch Meertens Instituut stated that this percentage is an underestimation: 35% would be closer to the true figure.¹⁹ Of those who consulted an alternative practitioner, 22% went to a homeopath and 63% suffered from a chronic illness.¹⁸ Other reasons found (of those we investigated, see section 'Results') for why patients would consult a CAM practitioner

in addition to conventional care, were that they wish advice 'from a different angle', or they have doubts about mainstream healthcare.²⁰ In our study, 36.3% of all patients indicated a preference for CAM/homeopathy.

Among the 'best homeopathic cases', 56% of patients had suffered from their main complaint for ≥ 2 years, and 38% had suffered for ≥ 5 years. This confirms other findings that, even in patients with long-lasting complaints, it is worthwhile to consult a practitioner for individualised homeopathic treatment.¹

In our opinion, the above-mentioned findings, supported by our results, legitimise advancement of CAM/homeopathy as an integrated part of general health care in The Netherlands and in other countries with similar developments. Numbers of patients with chronic complaints and multiple diagnoses are expected to increase in the years to come.²¹ This enhances the urgency to stimulate practice-based research by all stakeholders, and to provide accessible and reliable CAM/homeopathy treatments. Identifying prognostic factors for better therapeutic success should be an important part of this process.

Patient-Reported Outcome Measures

The 7- and 9-point Likert scales (such as Outcome in Relation to Impact on Daily Living[ORIDL]) were previously validated to measure change of main complaint and general health in retrospect.²² There is, however, an academic discussion about the reliability of measuring change retrospectively: some argue it is unreliable 'because it depends on accurate memory of the past'; others state that 'patients' retrospective assessments are more sensitive' and 'correlate better with patient satisfaction and physical and biological indicators of change in disease state'.²² Alternatively, the Measure Yourself Medical Outcome Profile (MYMOP) was, among others, used in data collection projects in the United Kingdom (including MYMOP2 for long-term conditions), China and Germany (MYMOP-D).^{23–26} The MYMOP measures change in intensity of both main problem and general health. The patients assess their situation over 'the last week'. Thus, it is more than a 'snapshot', while it does not require accurate long-term memory of the past. The MYMOP is not suitable for

periodic or cyclical complaints, such as premenstrual symptoms.

Tools to Define 'Best Homeopathic Cases'

Despite the tools given to define 'best homeopathic cases', the majority of the doctors found it 'sometimes' difficult to attach this label to a therapeutic success. To facilitate this decision, sharing cases with colleagues and deciding by consensus could be helpful, as was done in previous projects in The Netherlands.²⁷⁻³⁰ The doctors who used the modified Naranjo algorithm evaluated it as a useful tool to assess a causal relationship between homeopathic medicine and improvement. The patients' scores on the Likert scale 'positive change of main complaint' strongly correlated with the doctor's adapted GHHOS score. This outcome suggests that these tools reliably measured positive changes in main complaint in the sub-group of 'best homeopathic cases'.

Case Collection

After the project, a conference was organised about practice-based registration and case-reporting in The Netherlands. Doctors were invited to summarise and share their 'best homeopathic cases', based on the registered data and additional information extracted from their own files, as a qualitative evaluation method. They were especially requested to report specific keynote symptoms that triggered the selection of the homeopathic medicine. The doctors were encouraged to use the HOM-CASE CARE checklist, and also the modified Naranjo algorithm to assess causal relation between the homeopathic medicine and the improvement or cure.¹⁴ A spin-off of the project will be to invite the participating doctors to publish case reports and assist them in the process. Good-quality case reports could be published in mainstream journals or added to databases for homeopathic clinical case collection. In the homeopathy community, several initiatives on case collection exist, such as the WissHom project by the German Scientific Society for Homeopathy (<http://www.wisshom.de/index.php?menuid=15>) and the Clinical File Collection (CLIFICOL) project (www.clificol.net), supported by the European Committee for Homeopathy (ECH).

'General' and 'Homeopathic' Prognostic Factors

By qualitative analysis, several diagnoses were associated with patient-perceived improvement in main complaint (+2/ +3)—see ► **Table 4**. These could be identified as 'potential *general* prognostic factors' for treatment success with CAM/homeopathy; however, larger numbers will be required to generalise this conclusion. More detailed exploration of the 66 'best homeopathic cases' in this study could identify specific keynote symptoms as '*homeopathic*' prognostic factors. 'Homeopathic' prognostic factors can be useful for designing targeted (semi-)individualised homeopathic treatment plans for clinical research, as was recommended from additional analysis of a clinical study on premenstrual syndrome.³¹

Additionally, quantitative analysis could be performed. With Bayes' theorem, the prognostic value of a keynote

symptom can be assessed, predicting therapeutic success with a specific (individually prescribed) homeopathic medicine. This was demonstrated in a practice-based research project in The Netherlands.³² Such quantitative analysis could be of great value in improving the accuracy of homeopathic medicine selection in daily practice and clinical research. The feasibility of both qualitative and quantitative prognostic factor research can be enhanced by proper computer software.³³

Electronic Registration in Daily Practice

To enable future case collection and prognostic factor analysis in individualised homeopathy, several features will be required of a practice-based electronic registration programme. First, using a professional database requires a minimum of time and effort for the professional to enter routine data. Second, the software has to offer a facility to enter homeopathic 'prognostic factors': i.e. 'keynote symptoms' indicating specific homeopathic medicines.¹² In other CAM therapies, such as acupuncture or neural therapy, several individual traits could be defined as prognostic factors. Based on previous experience, we estimate that in routine practice with long-term registration, a maximum of three potential prognostic factors per patient would be feasible. In short-term research projects, a maximum of 10 might be feasible. Third, it is necessary to measure health changes by reliable parameters, both for continuous evaluation and for short-term research projects. Those three features together would enable systematic prognostic factor analysis of 'general' as well as 'homeopathic' (or other CAM-related) prognostic factors.³⁴

In conventional medicine also, there is increasing awareness of the need to standardise registration of data and invest in an electronic infrastructure.³⁵ Apart from the issues discussed above, when patient data are used for research, informed consent must be obtained, privacy issues must be solved and secure data storage guaranteed, according to regulations that apply in the region where the data are collected.

Conclusions

It is feasible to register (co-)diagnoses, chronicity, treatments and outcomes in homeopathic medical practice and to identify 'best homeopathic cases' using pre-defined criteria. A 7-point Likert scale to assess patient-perceived change of main complaint was evaluated as useful and this confirms outcomes of other studies. An adapted GHHOS scale was evaluated as a suitable tool to identify 'best homeopathic cases' by most doctors, along with other descriptive criteria. By the doctors who used it, the modified Naranjo algorithm was evaluated as a useful tool to assess causality. The HOM-CASE extension of the CARE checklist proved a helpful tool to summarise and report 'best cases'.

An electronic database should be adequate for a representative number of CAM practitioners to record patient data with minimum effort and time investment. Such a database would facilitate understanding why patients use specific

CAM modalities. To assess what patient characteristics are related to specific successful treatments requires optimising the user-friendliness of the database.

Highlights

- In a Dutch data collection pilot project with 399 patients, 66 'best homeopathic cases' were identified.
- Tools to define 'best homeopathic cases' were found useful.
- The patients' perceived improvement score was positively correlated with the doctors' assessment score for 'best homeopathic case.'
- Electronic registration databases should include the possibility to record homeopathic 'keynote symptoms' as prognostic factors.
- This could help to inform clinical research and improve homeopathic treatment by prognostic factor analysis.

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