A randomized comparison of homoeopathic and standard care for the treatment of glue ear in children

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SUMMARY. Objective: To pilot a model for determining whether homoeopathic treatment of children suffering from glue ear is more effective than standard GP care at producing a return to normal hearing (a hearing loss of less than 20dB) within 12 months. Design: Non-blind, randomized controlled trial. Setting: General practice in two locations in southern England. Subjects: Thirty-three children aged 18 months to 8 years with otitis media with effusion, hearing loss >20dB and an abnormal tympanogram. Outcome measures: Hearing loss, tympanogram, referrals to specialists and number of courses of antibiotics at 12 month follow-up. Results: A higher proportion of children receiving homoeopathic care had a hearing loss less then 20dB at follow-up (64 vs 56%), though this difference did not reach statistical significance (95% confidence interval for the difference between means of –25 and 42%). More homoeopathy patients than controls had a normal tympanogram (75 vs 31%, $P = 0.015$). Referrals to specialists and antibiotic consumption was lower in the homoeopathy group, though differences between groups did not reach statistical significance. Conclusion: Further research comparing homoeopathy to standard care is warranted. Assuming recovery rates of 50 and 30% in homoeopathy and standard care groups respectively, 270 patients would be needed for a definitive trial.
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INTRODUCTION

A recent review of the effectiveness of treatment for 'glue ear' – otitis media with effusion (OME) – reported that it is the most common cause of hearing impairment and elective surgery in children. The review recommended the conduct of 'large multicentre trials examining the effectiveness of a range of interventions'.[1]

Homoeopaths have long claimed to provide an effective treatment for glue ear. Moskovitz, for example, states that: 'homoeopathic remedies are wonderfully effective, both at the time of acute episodes of otitis media and constitutionally to prevent or minimize their number and severity'.[2] Neustaedter claims that: 'homoeopathic medicine provides a wide range of approaches to OME including remedies for acute otitis episodes constitutional treatment for the underlying susceptibility, and specific remedies prescribed on the basis of localized signs and symptoms in the middle ear'.[3]

However, a recent randomized trial of the effectiveness of homoeopathy in the treatment of upper respiratory infection did not find large differences between children treated with homoeopathy and those given placebo.[4] The authors concluded that 'individually prescribed homoeopathic medicines seem to add little to careful counselling of children with recurrent upper respiratory tract infection in reducing the daily burden of symptoms, use of antibiotics, and need for adenoidectomy and tonsillectomy'.

We were interested in assessing the effects of the homoeopathic intervention as a whole, including 'careful counselling', on glue ear in children. To our

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knowledge, only one paper has been published which has attempted to do so. Friese et al. compared 103 children with otitis media undergoing homoeopathic treatment with 28 seeing a conventional doctor. Duration of pain and number of recurrences was slightly better on homoeopathy, but differences between the groups did not reach statistical significance. The trial was not randomized, so that differences in outcome (or lack thereof) may result from differences between groups at baseline. We aimed to improve on this design by randomizing participants to homoeopathy or standard treatment. The question we ask in this pilot study is whether homoeopathic treatment of children suffering from glue ear is more effective than standard GP care at producing a return to normal hearing (a hearing loss of <20dB) within 12 months.

METHODS

Patients were recruited in the Isle of Wight via routine audiological screening conducted by the Audiology Service, Department of Community Paediatrics (St. Mary's NHS Trust). In Swindon, patients were recruited by the Ear, Nose and Throat (ENT) specialist at St. Margaret's Hospital, Swindon. The criteria for inclusion were: a positive diagnosis of OME by the patient's GP; hearing loss >20dBHL; an abnormal tympanogram (i.e. flat with absent reflexes) and patients in the age range 18 months to 8 years of age. Patients were excluded if they had a congenital abnormality affecting the ears or throat; Down's syndrome or other substantial abnormalities; a history of surgical interventions (e.g. adenoidectomy, tonsillectomy or grommet insertion) or tympanic membrane disease.

The researchers both received approval of the protocol from their respective ethics committees: the Local Research Ethics Committee for Swindon and the Local Research Ethics Committee for the Isle of Wight. The approval required the written consent of all parents/guardians of the patients involved. Information was also sent to the patients' GPs.

In the Isle of Wight, 50 patients were referred by the Department of Community Paediatrics but only 14 met the entry criteria. These patients were then randomized equally to standard care and homoeopathic treatment groups. In Swindon, 12 children were randomized to the homoeopathic treatment group and nine to the standard care group. In the Isle of Wight randomization was carried out by an impartial assistant and in Swindon it was carried out by the ENT Surgeon. In Swindon the standard care and homoeopathic care groups were randomized on an 'alternate basis'. In the Isle of Wight sealed envelopes were used for the randomization. All patients (and their guardians/parents) were informed of the random allocation at the time of their agreement to participate in the trial. Both the patients in the standard care and homoeopathic care groups were aware of which groups they had been allocated to. There was no blinding of the patients participating in the trial.

The two groups were treated with either homoeopathy or standard care. The latter involved a 'watch and wait' policy with auto inflation of ears, and in some cases a course of low-dose antibiotics for 4–6 weeks. Where there was no substantial improvement in 6–12 months, grommets were inserted. Homoeopathic treatments comprised an initial consultation lasting 1–1.5 hours in addition to follow-ups at monthly intervals. The researchers are both qualified and experienced homoeopathic practitioners, registered members of the Society of Homoeopaths and have some experience of treating children with upper respiratory infections and otitis media. The practitioners used classical homoeopathy involving both constitutional and acute prescribing based on treating the totality of the patients' symptoms. Patients receiving homoeopathic care were free to see their GPs as normal.

All participants in the trial were seen at 3 and 6 monthly examinations in order to record audiometric and tympanometric changes from the initial baseline diagnosis. In Swindon, those measurements were conducted by the ENT surgeon whereas in the Isle of Wight they were carried out by the Audiology Department (Community Paediatrics). Persons conducting the audiometric and tympanometric measurements were blinded to the treatment allocations of each participant. A treatment success was defined as a hearing loss of ≤20 dB at the 12 month follow-up.

Table 1 Age of participants

Age in years	Homoeopathic care group	Standard care group
<2	2	2
2	3	2
3	2	1
4	3	0
5	4	2
6	2	6
7	0	2
8	1	0
9	0	1
	17	16

Table 2 Audiometric measurements at initial diagnosis

Initial hearing loss	Homoeopathic care group	Standard care group
20–30 dB	1 (5.8%)	7 (43.7%)
30–40 dB	6 (35.2%)	5 (31.3%)
>40 dB	10 (58.8%)	4 (25%)

Table 3 Audiometric measures of participants after 12 months

	Homoeopathic care group	Standard care group
<20 dB	11 (64.7%)	9 (56.2%)
>20 dB	6 (35.3%)	7 (43.7%)

Table 4 Tympanogram measures after 12 months

	Homoeopathic care group	Standard care group
Normal	13 (76.4%)	5 (31.3%)
Fluid	4 (23.5%)	2 (12.5%)
Flat	0 (0%)	9 (56.2%)

Table 5 Courses of antibiotics in 12 months

	Homoeopathic care group	Standard care group
1 or more	5 (39.4%)	9 (56.2%)
none	12 (70.6%)	7 (43.7%)

Table 6 Referrals to specialists

	Homoeopathic care group	Standard care group
Myringotomy/grommets	3 (17.6%)	5 (31.3%)
Speech therapy	0 (0%)	1 (6%)

RESULTS

Two patients withdrew from the Swindon homoeopathic treatment group. Data was available for all other patients. Patients in the homoeopathic group received a median of seven treatments, with a range of from six to nine. Ages are comparable between groups (see Table 1)

Audiometric measurements of both groups of patients taken at the point of initial diagnosis are shown in Table 2. The homoeopathic care group had a higher degree of hearing loss at first diagnosis compared with the standard care group: 94% had a hearing loss >30 db as compared with 56.2% of the standard care group. The difference between groups is significant ($\chi^2 = 7$; P=0.03 by Fisher's exact test). This provides some evidence that there may have been interference with randomization.

As can be seen from Table 3, a higher proportion of the homoeopathic care group had a hearing loss of <20 dB after 12 months (difference between means 8.5%; 95%, CI –24.8, 41.7%). This difference does not reach statistical significance ($\chi^2 = 0.246$; P>0.2).

The data for tympanogram measures after 12 months are given in Table 4. The difference between groups is significant ($\chi^2 = 6.8$; P=0.015 by Fisher's exact test). Forty-five per cent more subjects in the homoeopathy group had a normal tympanogram than controls (95%, CI –14.8, 75.6%).

In addition to the above outcome measures, the study collected data as to the number of patients receiving antibiotics and other clinical interventions during and after treatment (Table 5). The difference between proportions for use of antibiotics is 26.8% in favour of homoeopathy (95%, CI –5.7, 59.4%). The results misses statistical significance ($\chi^2 = 2.4$; P=0.16 by Fisher's exact test).

More children in the standard care group were referred to specialists (Table 6). The difference between proportions is 19.9% (95%, CI –50, 10%) which does not reach statistical significance ($\chi^2 = 1.4$; P>0.2 by Fisher's exact test).

DISCUSSION

Owing to the small numbers participants involved in this pilot, it is not possible to draw firm conclusions. However, it is possible to note some trends in the data gathered. Differences between groups were larger for tympanogram measures than for audiometric improvement. There also seemed to be lower use of antibiotics in the homoeopathy group and less referral to specialist care.

This study was compromised by the possibility that randomization was unconcealed. The use of

alternate randomization and sealed envelopes made it possible for a recruiter to become aware of the allocation of a subject before they were entered into the trial. The uneven distribution in hearing loss at baseline provides some evidence that randomization concealment may have occurred.

In a definitive trial, randomization should take place by an independent study centre using a method such as telephone randomization. This ensures that those recruiting patients are not able to predict allocation before entering a subject nor change allocation afterwards.

The results of the trial suggest that defining a successful outcome only in terms of audiometric assessment is not sufficiently sensitive to distinguish between groups. It is recommended that a successful outcome is defined as both a hearing loss of <20 dB and a normal tympanogram. The trial allows some sample-size calculations to be undertaken. Assuming that 30% of children in the standard care group recover at the end of 12 months and a minimally clinical significant difference of 20%, 270 patients would have to complete a trial to have a 90% power of detecting a difference significant at 5%. For a larger difference of 30% between groups, 125 patients would have to be recruited.

In conclusion, the current trial provides some evidence that a package of homoeopathic care is more effective than standard care alone at treating glue ear in children. A larger trial with better control of randomization is required for a more definitive answer.

ACKNOWLEDGEMENTS

The project was funded by the Research Council for Complementary Medicine as part of a 'First Rung Award'. Andrew Vickers undertook the statistical analysis but was not involved in the day-to-day running of the trial.

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