

Proposed checklist for standardising homoeoprophylaxis interventions

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Abstract

Background: Results from large homoeoprophylaxis (HP) interventions support the effectiveness of HP, but their variable methodology means that meaningful summaries of the combined data are difficult to produce. **Objective:** The aim of this article is to develop possible ways of standardising and improving the quality of data from HP interventions. **Methods:** Evidence collected from some large HP interventions is summarised. A previously suggested pre- and post-intervention checklist intended to help standardise the evidence from HP interventions is critically examined. **Results:** A summary of HP evidence from large interventions shows that there is a growing body of data suggesting a level of HP effectiveness between 85% and 90%. However, the type and quality of the evidence is variable. A previously developed checklist for researchers to use is modified and examples are given from actual interventions. **Conclusion:** There is a growing body of evidence supporting claims that HP interventions are effective. The evidence base needs to be improved in a range of ways. Requiring a standardised checklist to be completed by researchers before and after an intervention offers one method to improve the quality and consistency of evidence collected. HP has much to offer governments, health officials and citizens globally. It is safe, relatively effective, flexible, easily delivered and highly cost-effective. Yet, it is supported by very few governments. The quantity of evidence is growing, but the onus is on proponents to strengthen the quality of the evidence base supporting HP to the point where the inevitable critics of Homoeopathy are silenced.

Keywords: Checklist, Effectiveness, Homoeoprophylaxis, Interventions, Research

INTRODUCTION

Hahnemann wrote passionately about his preference for infectious disease prevention (homoeoprophylaxis [HP]) over treatment: ‘Who can deny that the perfect prevention of infection from this devastating scourge, and the discovery of a means whereby this divine aim may be surely attained, would offer infinite advantages over any mode of treatment, be it of the most incomparable kind soever so ever? The remedy capable of maintaining the healthy uninfected by the miasm of scarlatina, I was so fortunate as to discover’.^[1]

If the reader substitutes ‘COVID-19’ for ‘scarlatina’, his statement stands as a goal for 2020. Already HP interventions are being used in India and Cuba. However, the proponents of HP have an obligation to produce high-quality evidence of effectiveness.

Respondents to a 2014/15 international survey of homoeopaths regarding HP were asked to: grade their confidence from 0 (none) to 10 (very strong) in the evidence available to

homoeopaths describing the safety and effectiveness of HP. High confidence (confidence ranked 8, 9 or 10) was: high confidence in HP safety: 69.4% and high confidence in HP effectiveness: 49.3%.^[2]

Pharmaceutical advocates would have even less confidence in the evidence base of HP, given the current dogma that Homoeopathy in general is ineffective.

Homoeopathic opponents of HP such as the Brazilian academic, Dr M Texiera, make extravagant claims against practitioners who use HP. Texiera claimed that users of HP ‘transgress the bioethical principles of beneficence and non-maleficence’. He also claimed that ‘In spite of promoting global use of so-called dynamized isoprophylaxis, Golden

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Received: 27.02.2020; Accepted: 02.05.2020; Published: 29.05.2020

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How to cite this article: Golden I. Proposed checklist for standardising homoeoprophylaxis interventions. Indian J Res Homoeopathy 2020;14:80-9.

Access this article online

Quick Response Code:



Website:
www.ijrh.org

DOI:
10.4103/ijrh.ijrh_18_20

reports rates of adverse effects higher than 10% in children subjected to this method – similar to those of conventional vaccination'.^[3] In fact, Golden's reported reaction rate per dose was 2%, whereas the per-dose reaction rate for vaccines can be as high as 82.84%.^[4]

Hence, there is a clear need to build confidence in HP, and this will require a stronger evidence base. We have a growing body of data from real-world interventions using HP, so the task of researchers is to continue to improve the quality of evidence so that the findings will be more widely accepted.

METHODS

Two publications in 2019 described 17 substantial HP interventions over 34 years in just three countries. There was

no attempt to list every HP intervention around the world – an impossible task. However, this small sample examined the use of HP in over 250 million people on an annualised basis – similar to 250 million prescriptions, except that many prescriptions were not just a single remedy given once, but a series of remedy administrations over time.^[5,6]

In 2018, the author suggested using a pre- and post-intervention checklist to improve the quality and standardisation of results. This is shown in Table 1.^[7]

It was decided to change the order of some items in the checklist, and then use two well-known epidemic HP interventions and the author's analysis of endemic HP to test to see how the pre- and post-intervention checklist would look.

Table 1: A suggested pre- and post-intervention checklist

Number	Item	Details/questions	Yes	No	NA/don't know
1	Title	State the title of the study	-	-	-
2	Objectives	State the objectives of the study. Are they clear and focussed on an achievable outcome?			
3	Research Method	State the research method used	-	-	-
4	Randomised	YES or NO? If YES, give details			
5	Blinded	YES or NO? If YES, give details			
6	Controlled	YES or NO? If YES, give details			
7.1	Follow-up	YES or NO? If YES, give details			
7.2	Follow-up randomised	If a sample used, was it randomised?			
8	Prospective	Is the study prospective?			
9.1	Established	Is the method being tested established within Homoeopathy?			
9.2	Likely positive	State the pre-study odds of a positive effect. Are they strong?			
9.3	Effect size	State the likely effect size of the medicine and how determined. Is this adequate?			
9.4	Sample size	State the projected sample size. Is this adequate?			
9.5	Power	State the power calculation if any. Is this adequate?			
Number	Item	BIAS	Yes	No	NA/Don't Know
10.1	Selection bias	Show how this bias is dealt with. Is this adequate to eliminate the bias?			
10.2	Detection bias	Show how this bias is dealt with. Is this adequate to eliminate the bias?			
10.3	Observer bias	Show how this bias is dealt with. Is this adequate to eliminate the bias?			
10.4	Recall bias	Show how this bias is dealt with. Is this adequate to eliminate the bias?			
10.5	Response bias	Show how this bias is dealt with. Is this adequate to eliminate the bias?			
10.6	Confirmation bias	Show how this bias is dealt with. Is this adequate to eliminate the bias?			
10.7	Analysis bias	Show how this bias is dealt with. Is this adequate to eliminate the bias?			
10.8	Publication bias	Show how this bias is dealt with. Is this adequate to eliminate the bias?			
10.9	Follow-up bias	Show how this bias is dealt with. Is this adequate to eliminate the bias?			
11	Confounders	List the possible confounders and how they will be dealt with. Have confounders been dealt with adequately?			
12	Statistical methods	List the statistical methods of analysis that will be used. Are they accepted and comprehensive methods?			
Number	Item	After completion of the study	Yes	No	NA/Don't Know
C1	Results	State the results of the study	-	-	-
C2	Strength	State the strength of the method	-	-	-
C3	Confidence	State the confidence limits of the result. Are they adequate?			
C4	Consistency	State how the results compare with other evidence. Are the results consistent with other evidence?			
C5	Biological gradient	Do the results reveal a positive dose-response?			
C6	Plausibility	Is the method biologically plausible?			
C7	Applicability	Can the results be translated to clinical practice?			

N/A: Not available

RESULTS

Interested readers who wish to study the full results from the interventions cited are directed to the original articles, but Table 2 shows that the HP interventions studied were a mix of non-randomised and controlled/not-controlled methodologies. The figures show the number of interventions in each category and the number of years for which the interventions ran.

Table 3 shows the references to the articles referred to in Table 2.

An analysis^[6] showed that there was consistency when these results were summarised in different ways, as shown in Table 4.

Table 5 shows the definitions of bias used in the following analysis. Different authors use terms differently.

A few examples of what a post-intervention checklist might look like are presented below. The first example [Table 6] uses the author's study of long-term/endemic HP in Australia,^[20] the second [Table 7] examines the leptospirosis intervention in Cuba in 2008^[21] and the third example [Table 8] examines the meningococcal meningitis intervention in Brazil in 1998.^[8] Another two examples are from studies conducted in India: one on Japanese Encephalitis (JE)^[22] in Andhra Pradesh and Telangana states [Table 9] and another

on Chikungunya^[23] [Table 10]. These examples assume the intervention has been completed and the researchers have filled in the form.

DISCUSSION

The practical circumstances of each HP intervention will determine the most appropriate data collection methods to use, remembering that most HP interventions are not academic research studies, but practical attempts to save lives and prevent suffering in at-risk populations.

Schunemann *et al.* argued that while RCTs should generate data having the greatest internal validity (and lowest risk of bias), evidence should first be *direct* (or applicable), and that 'direct evidence from NRS (non-randomised studies) can provide equivalent (or potentially higher) confidence (i.e., quality) compared with indirect evidence from RCTs.'^[24]

In many cases, when the entire population is intervened, then randomisation is not possible, and not needed. However, the establishment of direct or an indirect control group is of great importance, especially to allow measures of the effectiveness of the intervention.

A well-constructed, non-randomised study can produce reliable results, especially if researchers focus on developing a strong control and minimising the effect of confounders and biases. The three examples presented show that the suggested checklists allow a ready identification of biases as well as encourage a more consistent response and the calculation of meaningful measure of effectiveness.

CONCLUSION

The use of HP to prevent the spread of targeted infectious diseases is well established in Homoeopathy, being first used by Dr Hahnemann in 1798. However, the HP evidence base needs to be improved to increase confidence in its effectiveness among homoeopaths, health officials, politicians and citizens.

Table 2: Characteristics of interventions studied

Number, type and duration of interventions	Number and type of interventions			Duration of each intervention (years)	
	Randomisation			Randomisation	
	Yes	No	N/A	No	N/A
Direct control	0	3	2	3	2
No direct control					
Indirect control	0	2	3	7	13
No control	0	5	2	7	2
Total	0	10	7	17 years	17 years

N/A: Not available

Table 3: References for each type of non-randomised intervention, by year(s), by disease targeted, by country and by duration if greater than 1 year

	Randomisation	
	No	N/A
Direct control	1974 Meningococcal (B) ^[8] 1998 Meningococcal (B) ^[9] 2006 Chikungunya (I) ^[10]	2007 Epidemic Fever (I) ^[11] 2009 Dengue (C) ^[12]
No direct control		
Indirect control	2001 Dengue (B) ^[13] 2007 Dengue (B - Rio) (6 years) ^[14,15]	2007 Leptospirosis (C) ^[12] 2008 Leptospirosis (C) ^[12] 1999-09 Jap. Enceph. (I) (11 years) ^[16]
No control	2007 Hepatitis A (C) ^[12] 1989/91/93 Jap. Enceph. (I) (3 years) ^[17] 1996 Dengue (I) ^[18] 2012 Dengue (I) ^[18,19] 2007 Dengue (B - Sao Jose) ^[13]	2010 Swine Flu (C) ^[12] 2010 Pneumococcal (C) ^[12]

All interventions for 1 year unless stated otherwise. B=Brazil; C=Cuba; I=India

Golden: Proposed checklist for HP interventions

#	Effectiveness (%)	What was measured
A	90.4	Long-term HP effectiveness
B	86.2	Average of percentages of effectiveness in epidemic situations
C	88.0	Average of qualitative measures of effectiveness in epidemic situations

HP: Homoeoprophylaxis

Bias	Definition
Selection	Sample is not representative of the population
Detection	Observations in one group are not sought as diligently as in the other
Observer	The observer is able to be subjective about the outcome
Recall (allocation)	Patients know which group they have been allocated to
Response (enrolment)	Patients who enrol in a trial may not represent those of the population as a whole
Confirmation	A researcher forms a hypothesis or belief and uses respondents' information to confirm that belief
Analysis	The project rules are changed to produce certain outcomes
Publication	Negative studies less likely to be submitted and/or published
Follow-up	Subjects are not followed up

Number	Item	Details/question asked/comments	Yes	No	NA/?
1	Title	Effectiveness of long-term HP	-	-	-
2.1	Objectives	To assess the effectiveness of long-term HP in Golden's patients	X		
2.2	Variables assessed	Incidence of targeted infectious diseases. Assessment of likely exposure to the disease. Whether HP remedy given prior to exposure	-	-	-
3	Research Method	Prospective cohort study	-	-	-
4	Randomised	Whole group was studied			NA
5	Blinded	Every participant received the intervention		X	
6	Controlled	No direct control. Post-study, incidence of some diseases compared with national attack rates	X	X	
7.1	Follow-up	Non-respondents and significant responses followed up	X		
7.2	Follow-up randomised	If follow-up sample, was it randomised?			NA
8	Prospective	Is the study prospective?	X		
9.1	Established	Is the method being tested established within Homoeopathy?	X		
9.2	Likely positive result	Highly likely positive result given 220 years' experience	X		
9.3	Effect size	Around 85-90% effectiveness established in numerous studies	X		
9.4	Sample size	Over 1000 participants	X		
9.5	Power	What was the study power if calculated. Is it adequate?			NA
10	Confounders	Parental attitudes and responses; memory; accuracy of diagnosis. 7-step checking procedures used to minimise the impact of confounders	X		
11	Statistical methods	Means, averages, Chi-squared %, measure of effectiveness	X		
Number	Item	BIAS - was it dealt with?	Yes	No	NA
12.1	Selection bias	All participants were surveyed	X		
12.2	Detection bias	Non-respondents were re-surveyed	X		
12.3	Observer bias	Parental observations were subjective		X	
12.4	Recall (allocation) bias	No allocation to groups			NA
12.5	Response bias	Whole group surveyed			NA
12.6	Confirmation bias	All responses were tabulated and published	X		
12.7	Analysis bias	Simple statistics used and published	X		
12.8	Publication bias	Failures and negative comments/results published	X		
12.9	Follow-up bias	All significant responses followed up to confirm in the last 5 years	X		
Number	Item	After completion of the study	Yes	No	NA/?
C1	Results	90.4% effectiveness	-	-	-

Contd...

Table 6: Contd...

Number	Item	Details/question asked/comments	Yes	No	NA/?
Number	Item	After completion of the study	Yes	No	NA/?
C2	Confidence	95% CI 87.3%-93.2%	X		
C3	Strength of association	There is a strong association between receiving HP and not being affected by exposure to a targeted disease	X	-	-
C4	Consistency	Other published evidence suggests effectiveness of HP at around 85-90%	X		
C5	Biological gradient	Failures are highest in those with fewest doses	X		
C6	Plausibility	There is debate over the biological plausibility of Homoeopathy in general, as well as HP specifically			?
C7	Applicability	The results have been translated to clinical practice	X		

HP: Homoeoprophylaxis, CI: Confidence interval

Table 7: Example 2: Leptospirosis in Cuba, 2008

Number	Item	Details/questions asked/comments	Yes	No	NA/?
1	Title	Effectiveness of 2008 HP intervention against leptospirosis in Las Tunas, Holguin and Granma Provinces, Cuba	-	-	-
2.1	Objectives	To assess the effectiveness of the 2008 HP intervention against leptospirosis in Cuba	X		
2.2	Variables assessed	Notifications and deaths from leptospirosis. Percentage of population receiving HP	-	-	-
3	Research Method	Retrospective whole-population study	-	-	-
4	Randomised	Whole group studied			NA
5	Blinded	Entire population offered the intervention		X	
6	Controlled	No direct control. Post-study, incidence of leptospirosis compared with national attack rates	X	X	
7.1	Follow-up	No follow-up		X	
7.2	Follow-up randomised	If follow-up sample, was it randomised?			NA
8	Prospective	Is the study prospective?		X	
9.1	Established	Is the method tested established within Homoeopathy?	X		
9.2	Likely positive result	Highly likely positive result given 200 years' experience	X		
9.3	Effect size	Around 85%-90% effectiveness from numerous studies	X		
9.4	Sample size	Over 2,200,000 participants	X		
9.5	Power	What was the study power if calculated. Is it adequate?			NA
10	Confounders	Some participants vaccinated; chemoprophylaxis; weather analysis; national publicity campaign. Published analysis shows minimal impact of confounders on overall results	X		
11	Statistical methods	Means, averages, comparative tables and graphs	X		
Number	Item	BIAS - was it dealt with?	Yes	No	N/A
12.1	Selection bias	All residents offered intervention, acceptance was voluntary. Bias due to self-selection by residents		X	
12.2	Detection bias	All cases would have presented to hospital eliminating this bias	X		
12.3	Observer bias	Tests undertaken in hospitals/laboratories	X		
12.4	Recall bias	No allocation to groups			NA
12.5	Response bias	Whole group surveyed			NA
12.6	Confirmation bias	Responses were tabulated and published	X		
12.7	Analysis bias	Simple statistics used and published	X		
12.8	Publication bias	Failures were published	X		
12.9	Follow-up bias	No follow-up			NA
Number	Item	After completion of the study	Yes	No	NA/?
C1	Results	Comparative results showed high effectiveness	-	-	-
C2	Confidence	Not calculated		X	
C3	Strength of association	There is a strong association between receiving HP and not being affected by exposure to a targeted disease	X	-	-
C4	Consistency	Other published evidence suggests effectiveness of HP at around 85-90%	X		
C5	Biological gradient	Failures are highest in those with no doses	X		
C6	Plausibility	There is debate over the biological plausibility of Homoeopathy in general, as well as HP specifically			?
C7	Applicability	The results have been translated to clinical practice	X		

HP: Homoeoprophylaxis

Table 8: Example 3: Meningococcal meningitis in Brazil, 1998

Number	Item	Details/questions asked/comments	Yes	No	NA/?
1	Title	Meningococcinum: Its protective effect against meningococcal disease in Brazil	-	-	-
2.1	Objectives	To assess the effectiveness of the HP intervention in 1998	X		
2.2	Variables assessed	Notifications and deaths from meningococcal disease. Percentage of cohort receiving HP	-	-	-
3	Research Method	Prospective cohort study (infants to 20 years of age)	-	-	-
4	Randomised	Participation was elective, no randomisation		X	
5	Blinded	Entire population offered the intervention. No placebo		X	
6	Controlled	Direct control with residents not choosing intervention	X		
7.1	Follow-up	At 6 and 12 months following intervention	X		
7.2	Follow-up randomised	Follow-up involved the entire cohort			NA
8	Prospective	Is the study prospective?	X		
9.1	Established	Is the method being tested established within Homoeopathy?	X		
9.2	Likely positive result	Highly likely positive result given 200 years' experience	X		
9.3	Effect size	Around 85-90% effectiveness established in numerous studies	X		
9.4	Sample size	89,365 cohort, 65,826 participants	X		
9.5	Power	What was the study power if calculated. Is it adequate?			N/A
10	Confounders	Self-selection of participation, no blinding	X		
11	Statistical methods	Means, averages, comparative tables and graphs, measure of effectiveness	X		
Number	Item	BIAS - was it dealt with?	Yes	No	N/A
12.1	Selection bias	All residents offered intervention. Self-selection occurred		X	
12.2	Detection bias	All cases were noted irrespective of from which group	X		
12.3	Observer bias	Tests and examinations undertaken in hospitals. Bias unlikely but not impossible	X		
12.4	Recall bias	Patients (or parents in the case of infants) know to which group they belong		X	
12.5	Response (enrolment) bias	Patients (or parents) chose to receive the nosode		X	
12.6	Confirmation bias	Responses were tabulated and published. Bias unlikely but not impossible	X	X	
12.7	Analysis bias	Simple statistics used and published	X		
12.8	Publication bias	Failures were published	X		
12.9	Follow-up bias	Cohort followed for 12 months. All cases reporting to hospital were recorded	X		
Number	Item	After completion of the study	Yes	No	NA/?
C1	Results	95% after 6 months and 91% after 12 months	-	-	-
C2	Confidence	Not calculated		X	
C3	Strength of association	There is a strong association between receiving HP and not being affected by exposure to a targeted disease	X	-	-
C4	Consistency	Published evidence effectiveness of HP at 85-90%	X		
C5	Biological gradient	Failures are highest in those with no doses	X		
C6	Plausibility	There is debate over the biological plausibility of Homoeopathy in general, as well as HP specifically			?
C7	Applicability	The results have been translated to clinical practice	X		

HP: Homoeoprophylaxis

Table 9: Example 4: Japanese Encephalitis in India, 1999 to 2009

No.	Item	Details/Questions asked/Comments	Yes	No	NA/?
1	Title	HP Intervention Against Japanese Encephalitis (JE) in Andhra Pradesh and Telangana (AP and T)	-	-	-
2.1	Objectives	To assess the effectiveness of the 1999 to 2009 HP intervention against JE in AP and T in children aged under 15 years.	X		
2.2	Variables assessed	Notifications and deaths from JE. Percentage of population receiving HP.	-	-	-
3	Research Method	Prospective whole-cohort study.	-	-	-
4	Randomised	Whole group studied.			NA
5	Blinded	Entire population offered the intervention.		X	
6	Controlled	No direct control. Post study, incidence of JE compared with attack rates in surrounding States.		X	
7.1	Follow-up	No follow-up		X	
7.2	Follow-up randomised	If follow-up sample, was it randomised?			NA

Contd...

Golden: Proposed checklist for HP interventions

Table 9: Contd...					
No.	Item	Details/Questions asked/Comments	Yes	No	NA/?
8	Prospective	Prospective study	X		
9.1	Established	The method tested is established within homoeopathy?	X		
9.2	Likely positive result	Highly likely positive result given 200 years experience	X		
9.3	Effect size	Around 85-90% effectiveness from numerous studies.	X		
9.4	Sample size	Over 30,000,000 participants over 11 years.	X		
9.5	Power	What was the study power if calculated. Is it adequate?			NA
10	Confounders	Some participants vaccinated	X		
11	Statistical methods	State statistics showing incidence and deaths from JE. Comparative tables and graphs. Historical trends	X		
No.	Item	BIAS - was it dealt with?	Yes	No	N/A
12.1	Selection bias	All eligible residents offered intervention, acceptance was voluntary. Bias due to self selection by parents		X	
12.2	Detection bias	All cases would have presented to hospital eliminating this bias	X		
12.3	Observer bias	Tests undertaken in hospitals/laboratories	X		
12.4	Recall bias	No allocation to groups			NA
12.5	Response bias	Whole group surveyed			NA
12.6	Confirmation bias	Responses were tabulated and published	X		
12.7	Analysis bias	Simple statistics used and published	X		
12.8	Publication bias	Failures were published	X		
12.9	Follow-up bias	No follow-up			NA
No.	Item	After completion of the study	Yes	No	NA/?
C1	Results	Comparative results with other States as well as historical trends showed high effectiveness	-	-	-
C2	Confidence	Not calculated		X	
C3	Strength of association	There is a strong association between receiving HP and not being affected by exposure to a targeted disease	X	-	-
C4	Consistency	Other published evidence suggests effectiveness of HP at around 85-90%	X		
C5	Biological gradient	Failures expected to be highest in those with no doses, but data identifying recipients and non-recipients not available.			N/A
C6	Plausibility	There is debate re the biologically plausibility of homoeopathy in general, as well as HP specifically			?
C7	Applicability	The results have been translated to clinical practice	X		

Table 10: Example 5: Chikungunya in India, 2014					
No.	Item	Details/Questions asked/Comments	Yes	No	NA/?
1	Title	Homoeopathic Genus Epidemicus 'Bryonia alba' as a prophylactic during an outbreak of Chikungunya in India: A cluster-randomised, double-blind, placebo-controlled trial	-	-	-
2.1	Objectives	To assess the effectiveness of the 2007 HP intervention against Chikungunya in Kerala in children aged under 15 years	X		
2.2	Variables assessed	Notifications and deaths from Chikungunya in active and placebo clusters.	-	-	-
3	Research Method	A cluster-randomised, double-blind, placebo-controlled trial	-	-	-
4	Randomised	Remedy distribution randomised	X		
5	Blinded	Double blinded	X		
6	Controlled	Placebo controlled	X		
7.1	Follow-up	Weekly follow-up for 35 days	X		
7.2	Follow-up randomised	All participants followed up			NA
8	Prospective	prospective	X		
9.1	Established	The method tested is established within homoeopathy?	X		
9.2	Likely positive result	Highly likely positive result given 200 years experience	X		
9.3	Effect size	Around 85-90% effectiveness from numerous studies.	X		
9.4	Sample size	Over 38,229 participants	X		
9.5	Power	What was the study power if calculated. Is it adequate?			NA
10	Confounders		X		

Contd...

Table 10: Contd...

No.	Item	Details/Questions asked/Comments	Yes	No	NA/?
11	Statistical methods	The event rate, standard error, standard deviation, intervention effects, difference in event rate and 95% CI of intervention and control group were estimated following the cluster analysis methodology. ^[15] Independent sample <i>t</i> -test was performed to analyze the cluster level event rates. The <i>P</i> ≤0.05 was considered to be significant	X		
No.	Item	BIAS - was it dealt with?	Yes	No	N/A
12.1	Selection bias	The cohorts were representative of the area being studied	X		
12.2	Detection bias	Randomised cohorts	X		
12.3	Observer bias	There was no laboratory confirmation of cases		X	
12.4	Recall bias	Participants were blinded	X		
12.5	Response bias	All eligible residents were entered	X		
12.6	Confirmation bias	Responses were tabulated and published	X		
12.7	Analysis bias	Simple statistics used and published	X		
12.8	Publication bias	Failures were published	X		
12.9	Follow-up bias	Regular follow-ups were conducted	X		
No.	Item	After completion of the study	Yes	No	NA/?
C1	Results	<i>Bryonia alba</i> 30C as genus epidemicus was better than placebo in decreasing the incidence of chikungunya in Kerala	-	-	-
C2	Confidence	<i>P</i> =0.03	X		
C3	Strength of association	There is a modest association between receiving HP and not being affected by exposure to a targeted disease		X	
C4	Consistency	Other published evidence suggests effectiveness of HP at around 85-90%	X		
C5	Biological gradient	Failures higher in those in the placebo group	X		
C6	Plausibility	There is debate re the biological plausibility of homeopathy in general, as well as HP specifically			?
C7	Applicability	The results can be translated to clinical practice	X		

It is suggested that a pre- and post-intervention checklist will assist that goal and allow more effective analysis of the overall effectiveness of this safe, adaptable, timely and cost-effective method.

Financial support and sponsorship

Nil.

Conflicts of interest

Isaac Golden has supplied homeoprophylaxis (HP) programmes to patients since 1985.

REFERENCES

- Hahnemann S. The cure and prevention of scarlet fever. In: Hahnemann's Lesser Writings. New Delhi: B Jain Publishers (P) Ltd.; 2007.
- Golden I, Stranieri A, Al Nuaimat A. Attitudes towards and use of homeoprophylaxis: Findings of two international surveys. *Int J High Dilution Res* 2015;14:38-53.
- Texiera M. Homeopathy: A preventive approach to medicine? *Int J High Dilution Res* 2009;8:155-72.
- GlaxoSmithKline Inc. Product Monograph Infanrix Hexa. 2018. p. 10 (Irritability any Grade). Available from: <https://ca.gsk.com/media/537989/infanrix-hexa.pdf>. [Last accessed on 2020 Feb 18].
- Golden I. Large homeoprophylaxis: Brief and long-term interventions. *Am J Homeopathic Med* 2019;112:31-6.
- Golden I. Large Homeoprophylaxis Interventions by Government Institutions. *Similia* 2019;31:14-9.
- Golden I. Observational research in homeopathy: Improving HP research outcomes. *Homeopathic Links* 2018;31:71-4.
- Castro D, Nogueira GG. Use of the nosode Meningococcinum as a preventative against meningitis. *J Am Institute Homeopathy* 1975;68:211-9.
- Mronisnski C, Adriano E, Mattos G. Meningococcinum: Its protective effect against meningococcal disease. *Homeopathic Links* 2001;14:230-4.
- Rejikumar R, Dinesh RS. Study on the Prophylactic Efficacy of Homeopathic Preventive Medicine Against Chikungunya Fever. Available from: <http://www.similima.com/pdf/efficacy-chiunguna-kerala.pdf>. [Last accessed on 2020 Feb 18].
- Protective Efficacy of "Genus Epidemicus" (Homeopathic Preventative) Administered During Epidemic Fever in Kerala. Available from: http://www.homeopathy.kerala.gov.in/docs/jan2011/raech_report.pdf. [Last accessed on 2020 Feb 18].
- Bracho G, Golden I. A brief history of homeoprophylaxis in Cuba, 2004-2014. *Homeopathic Links* 2016;29:128-34.
- Marino R. Homeopathy and collective health: The case of dengue epidemics. *Int J High Dilution Res* 2008;7:179-85.
- De Souza Nunes LA. Contribution of homeopathy to the control of an outbreak of dengue in Macaé, Rio de Janeiro. *Int J High Dilution Res* 2008;7:186-92.
- Dengue and Homeopathy: A Successful Experience from Macaé. Available from: <http://www.ecomedicina.com.br/site/conteudo/entrevista22.asp>. [Last accessed on 2020 Feb 18].
- Gadugu S, Nyapati SR, Sastry GL. An open observational study on efficacy of miasmatic prescription in the prevention of Japanese Encephalitis. *Homeopathy* 2014;103:78-9.
- Rastogi DP, Sharma VD. Study of homeopathic drugs in encephalitis epidemic (1991) in Uttar Pradesh (India). *CCRH Quarterly Bulletin* 1992;14:1-11.
- CCRH. Dengue Epidemic – Scientific Activities of Council. *CCRH News* 1996-97;23:10.
- The Hindu: Homeopathy to Fight Dengue Fever; 14 August, 2012. Available from: <https://www.thehindu.com/todays-paper/tp-national/tp-andhrapradesh/homeopathy-to-fight-dengue-fever/article3767663.ece>. [Last accessed on 2020 May 02].
- Golden I. The Potential Value of Homeoprophylaxis in the Prevention of Infectious Diseases, and the Maintenance of General Health in Recipients. Melbourne: Swinburne University Press; 2005.
- Bracho G, Golden I. A re-evaluation of the effectiveness of

- homoeoprophylaxis against leptospirosis in Cuba in 2007 and 2008. *J Evidence Based Comp Alt Med* 2014;19:155-60.
22. Oberai P, Varanasi R, Padmanabhan M, Upadhyaya A, Singh S, Singh SP. Effectiveness of Homeopathic Medicines as Addon to Institutional Management Protocol for Acute Encephalitis Syndrome in Children: An Open-Label Randomized Placebo Controlled Trial. *Homeopathy*. 2018; 107(3):161-171.
23. Nair KR, Gopinadhan S, Kurup TN, Bonthu SJ, Aggarwal A, Varanasi R, *et al.* Homoeopathic Genus Epidemicus 'Bryonia alba' as a prophylactic during an outbreak of Chikungunya in India: A cluster -randomised, double -blind, placebo- controlled trial. *Indian J Res Homoeopath*. 2014;8(3):160-5.
24. Schünemann HJ, Tugwell P, Reeves BC, Akl EA, Santesso N, Spencer FA, *et al.* Non-randomized studies as a source of complementary, sequential or replacement evidence for randomized controlled trials in systematic reviews on the effects of interventions. *Res Synth Methods* 2013;4:49-62.

होम्योप्रोफाइलैक्सिस हस्तक्षेपों के मानकीकरण के लिए प्रस्तावित जांचसूची

पृष्ठभूमि: बड़े होम्योप्रोफाइलैक्सिस (एचपी) हस्तक्षेपों से प्राप्त निष्कर्ष एचपी की प्रभावशीलता का समर्थन करता है परन्तु उनकी परिवर्तनीय पद्धति इंगित करती है कि संयुक्त आंकड़ों के अर्थपूर्ण सारांशों को निर्मित करना कठिन है।

उद्देश्य: इस लेख का उद्देश्य है, एचपी हस्तक्षेपों से प्राप्त आंकड़ों की गुणवत्ता को मानकीकृत करने और उनमें सुधार लाने के संभावित तरीकों को विकसित करना।

विधि: कुछ बड़े एचपी हस्तक्षेपों से एकत्रित साक्ष्यों को संक्षेप में प्रस्तुत किया गया है। एचपी हस्तक्षेपों से प्राप्त साक्ष्य के मानकीकरण में सहयोग करने के लिए पहले से सुझाए गये हस्तक्षेप से पूर्व एवं बाद की जांचसूची का परीक्षण गंभीरतापूर्वक किया गया।

परिणाम: बड़े हस्तक्षेपों से प्राप्त एचपी साक्ष्य का सारांश यह दर्शाता है कि आंकड़ों का एक बढ़ता हुआ समुच्चय है जो एचपी की प्रभावशीलता के स्तर को 85 प्रतिशत और 90 प्रतिशत के बीच रखने का सुझाव देता है। फिर भी, साक्ष्य का प्रकार और गुणवत्ता परिवर्तनीय है। शोधकर्ताओं के उपयोग के लिए पूर्व में विकसित जांचसूची को संशोधित किया गया है और वास्तविक हस्तक्षेपों से उदाहरण प्रस्तुत किये गये हैं।

निष्कर्ष: साक्ष्यों का एक प्रगतिशील समूह है जो इन दावों का समर्थन करता है कि एचपी के हस्तक्षेप प्रभावशाली होते हैं। साक्ष्य के आधार को विभिन्न उपायों से सुधारे जाने की आवश्यकता है। किसी हस्तक्षेप से पूर्व और पश्चात शोधकर्ताओं द्वारा एक मानकीकृत जांचसूची को पूरा करने की आवश्यकता एकत्रित साक्ष्य की गुणवत्ता और एकरूपता को उन्नत बनाने के लिए एक सुझाव है। एचपी के पास सरकारों, स्वास्थ्य अधिकारियों एवं नागरिकों को वैश्विक रूप से प्रस्तुत करने के लिए बहुत कुछ है। यह सुरक्षित, तुलनात्मक रूप से प्रभावशाली, लचीला, सरलता से प्रस्तुत किये जाने वाला और अत्यधिक लागत प्रभावी होता है। फिर भी, बहुत कम सरकारों द्वारा इसे समर्थन दिया जाता है। साक्ष्य की गुणवत्ता बढ़ रही है, परन्तु यह दायित्व समर्थकों का है कि वे साक्ष्य आधारित गुणवत्ता को उस बिंदु तक सुदृढ़ करें जहाँ से होम्योपैथी की अवश्यंभवी आलोचना मौन हो जाए।

Liste de contrôle proposée pour normaliser les interventions d'homœoprophylaxie

Contexte: Les résultats des grandes interventions d'homœoprophylaxie (HP) appuient l'efficacité de l'HP, mais leur méthodologie variable signifie qu'il est difficile de produire des résumés significatifs des données combinées. **Objectif:** Le but de cet article est de développer des moyens possibles de standardiser et d'améliorer la qualité des données des interventions HP. **Méthodes:** Les preuves recueillies à partir de certaines grandes interventions HP envergure sont résumées. Une liste de contrôle pré- et post-intervention précédemment suggérée, destinée à aider à normaliser les preuves des interventions HP, est analysée de manière critique. **Résultats:** Un résumé des preuves HP provenant des grandes interventions montre qu'il existe un nombre croissant de données suggérant un niveau d'efficacité HP compris entre 85% et 90%. Cependant, le type et la qualité des preuves sont variables. Une liste de contrôle développée précédemment pour les chercheurs est modifiée et des exemples sont donnés à partir d'interventions réelles. **Conclusion:** Il existe un nombre croissant de preuves étayant les affirmations que les interventions HP soient efficaces. La base de preuves doit être améliorée de différentes manières. Exigeant une liste de contrôle standardisée à remplir par les chercheurs avant et après une intervention offre une méthode pour améliorer la qualité et la cohérence des preuves collectées. HP a beaucoup à offrir aux gouvernements, aux responsables de la santé et aux citoyens du monde entier. Il est sûr, relativement efficace, flexible, facile à livrer et très rentable. Pourtant, il est soutenu par très peu de gouvernements. La quantité de preuves augmente, mais il incombe aux promoteurs de renforcer la qualité de la base de preuves soutenant l'HP au point où les critiques inévitables de l'homéopathie sont réduits au silence.

Lista de verificación propuesta para estandarizar las intervenciones de homeoprolifaxis

Antecedentes: Los resultados del homeoprolifaxis grande (HP) intervenciones apoyan la eficacia del HP, pero su metodología variable significa que es difícil producir resúmenes significativos de los datos combinados. **Objetivo:** El objetivo de este artículo es desarrollar posibles formas de estandarizar y mejorar la calidad de los datos de las intervenciones de HP. **Métodos:** Se resumen las pruebas recogidas de algunas intervenciones de HP de gran tamaño. Se examina críticamente una lista de comprobación antes y después de la intervención que se había sugerido previamente y que tenía por objeto ayudar a estandarizar la evidencia de las intervenciones de HP. **Resultados:** Un resumen de pruebas de HP de intervenciones grandes muestra que hay un cuerpo creciente de datos que sugieren un nivel de la eficacia de HP entre el 85% y el 90%. Sin embargo, el tipo y la calidad de la evidencia es variable. Se modifica una lista de verificación desarrollada previamente para que los investigadores la usen y se dan ejemplos de intervenciones actual. **Conclusión** Existe un creciente número de pruebas que respaldan las afirmaciones de que las intervenciones de HP son eficaces. La base de pruebas debe mejorarse de diversas maneras. Requerir que los investigadores completen una lista de verificación estandarizada antes y después de una intervención ofrece un método para mejorar la calidad y consistencia de la evidencia recogida. HP tiene mucho que ofrecer a los gobiernos, a los funcionarios de salud y a los ciudadanos en todo el mundo. Es seguro, relativamente eficaz, flexible, fácil de entregar y altamente económico. Sin embargo, es apoyado por muy pocos gobiernos. La cantidad de evidencia está creciendo, pero la responsabilidad es de los proponentes fortalecer la calidad de la base de evidencia que apoya a HP hasta el punto en que los críticos inevitables de la Homeopatía son silenciados.

Vorgeschlagene Checkliste zur Standardisierung von Homoeoprophylaxe-Interventionen

Hintergrund: Ergebnisse großer Homoeoprophylaxe-Interventionen (HP) unterstützen die Wirksamkeit von HP, aber ihre variable Methodik bedeutet, dass aussagekräftige Zusammenfassungen der kombinierte Daten sind schwer zu produzieren. **Ziel:** Ziel dieses Artikels ist es, Möglichkeiten zur Standardisierung und Verbesserung der Qualität von Daten aus HP Interventionen. **Methoden:** Die aus einigen großen HP-Interventionen gesammelten Beweise werden zusammengefasst. A zuvor vorgeschlagenen Checklisten vor und nach der Intervention, die dazu beitragen sollen, die HP Interventionen werden kritisch untersucht. **Ergebnisse:** Eine Zusammenfassung der HP-Nachweise aus großen Interventionen zeigen, dass es immer mehr Daten gibt, die auf ein HP-Niveau hindeuten Wirksamkeit zwischen 85 % und 90 %. Art und Qualität der Beweise sind jedoch Variable. Eine zuvor entwickelte Checkliste für Forscher wird modifiziert und Beispiele werden aus tatsächlichen Interventionen gegeben. **Fazit:** Es gibt immer mehr Belege dafür, dass HP-Interventionen wirksam sind. Die Evidenzbasis muss auf verschiedene Weise verbessert werden. Eine standardisierte Checkliste muss von Forscher vor und nach einer Intervention bietet eine Methode zur Verbesserung der Qualität und Konsistenz der gesammelten Beweise. HP hat Regierungen, Gesundheitsbeamten und Bürger weltweit. Es ist sicher, relativ effektiv, flexibel, leicht zu liefern und sehr kostengünstig. Dennoch wird sie von sehr wenigen Regierungen unterstützt. Die Zahl der Beweise wächst, aber die Befürworter sind es, die Qualität der Evidenzbasis zu stärken, die HP unterstützt, um der Punkt, an dem die unvermeidlichen Kritiker der Homöopathie zum Schweigen gebracht werden.

提出的清单为规范化Homoeoprophylaxis干预措施

背景: 结果从大homoeoprophylaxis (HP) 干预支持HP的有效率, 但他们易变的方法学意味着联合的数据的意味深长的总结是难生产。

客观: 这篇文章的目标将开发规范化和改进数据的质量可能的方式从HP干预。

方法: 从一些大HP干预收集的的证据总结。 早先建议的意欲的前和岗位干预清单帮助规范化证据从HP干预重要地被审查。

结果: HP证据总结从大干预表示, 有数据一个增长的身体建议HP有效率的水平在85%和90%之间.. 然而, 证据的种类和质量是易变的。 为了研究员能使用修改一个早先被开发的清单, 并且举例子从实际干预。

结论: 越来越多的证据支持HP干预措施是有效的说法。 证据基地在方式的范围需要被改进。 要求一个规范化的清单由研究员完成在干预前后提供一个方法改进收集的的证据质量和一贯性。 HP惠普有很多提供政府, 全球性卫生官员和公民. 它是安全的, 相对地有效, 灵活, 容易地交付和高度花费了有效。 然而, 非常少量政府支持它。 证据的数量正在增长, 但支持者有责任加强支持惠普的证据基础的质量, 以至于顺势疗法不可避免的批评者被压制。