

Is It Possible to Distinguish Homeopathic Aggravation from Adverse Effects? A Qualitative Study

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Keywords

Homeopathy · Aggravation · Adverse effects · Focus group interview · Safety · Risk assessment

Summary

Background: Homeopathic aggravation is a temporary worsening of existing symptoms following the administration of a correct homeopathic prescription. The aim of this study was to explore and compose criteria that may differentiate homeopathic aggravations from adverse effects. **Material and Methods:** A qualitative approach was employed using focus group interviews. 2 interviews, with 11 experienced homeopaths, were performed in Oslo, Norway. The practitioners have practiced classical homeopathy over a period of 10–32 years. Qualitative content analysis was used to analyze the text data. The codes were defined before and during the data analysis. **Results:** We found that aggravations were subtle and multifaceted events. Moreover, highly skilled homeopaths are required to identify and report aggravations. Adverse effect may be defined as an ‘undesirable effect of a remedy’. This definition is pragmatic, flexible, and more in line with the holistic paradigm that the homeopaths represent. 8 criteria that distinguish aggravation from adverse effect were found. Highly sensitive persons hold a unique position regarding safety, as it is important to identify these patients in order to treat them correctly and avoid undesirable effects of the treatment. **Conclusion:** This study rigorously explored homeopaths’ views and experience on aggravation and adverse effects. The 8 criteria developed in this study may ensure patient safety and support therapists in identifying an ‘undesirable effect of a remedy’.

Schlüsselwörter

Homöopathie · Erstverschlimmerung · Nebenwirkungen · Fokusgruppeninterview · Sicherheit · Risikobestimmung

Zusammenfassung

Hintergrund: Unter einer homöopathischen Erstverschlimmerung versteht man die zeitweilige Verschlechterung einer bereits bestehenden Symptomatik in Folge einer korrekten homöopathischen Behandlung. Das Ziel dieser Studie war die Entwicklung von Kriterien, mit deren Hilfe die Unterscheidung von einem unerwünschten Ereignis möglich ist. **Material und Methoden:** Die Untersuchung wurde mittels qualitativer Forschungsmethoden auf der Basis von Fokusgruppeninterviews durchgeführt. Mit 11 erfahrenen Homöopathen aus Oslo, die über 10–32 Jahre Erfahrung in der Anwendung klassischer Homöopathie aufwiesen, wurden jeweils 2 Interviews geführt. Die Texte wurden mittels qualitativer Inhaltsanalyse untersucht, und die entsprechenden Codes wurden sowohl vor als auch während der Datenanalyse entwickelt. **Ergebnisse:** Es zeigte sich, dass es langjähriger Erfahrung und einer hohen Sachkunde bedarf, um Erstverschlimmerungen zu identifizieren. Dabei wurden homöopathische Erstverschlimmerungen als sehr subtile und komplexe Ereignisse beschrieben. Als Definition eines unerwünschten Ereignisses wird der Begriff «unerwünschter Effekt eines homöopathischen Heilmittels» vorgeschlagen, da sich diese operationale Definition angemessen in das ganzheitliche Vorgehen eines homöopathischen Behandlungsansatzes integrieren lässt. Insgesamt wurden 8 Kriterien beschrieben, mit denen ein «unerwünschter Effekt eines homöopathischen Heilmittels» von einer Erstverschlimmerung unterschieden werden kann. Da besonders sensitive Personen/Patienten in Bezug auf Patientensicherheit eine Sonderstellung einnehmen, ist es wichtig, diese Patienten vor einer Behandlung korrekt zu identifizieren. **Schlussfolgerung:** Ziel dieser Untersuchung war es, Auffassungen, Beobachtungen und Erfahrungen bewanderter Homöopathen zu nutzen, um behandlungsabhängige Symptome bzw. deren Verschlechterung entweder als Teil der Behandlung oder als unerwünschte Ereignisse zu identifizieren. Zu diesem Zweck wurden 8 Kriterien entwickelt, deren Anwendung die Patientensicherheit erhöhen und Behandelnde dabei unterstützen kann, die Risiken der Behandlung besser abzuschätzen.

Introduction

Homeopathy is one of the most popular forms of complementary and alternative medicine (CAM) in Europe [1, 2], and is associated with high patient satisfaction [3, 4]. Homeopathic aggravation is a temporary worsening of existing symptoms following the administration of a correct homeopathic prescription and is usually followed by an improvement [5–7]. It indicates that the individual is responding to the medication by generating or increasing symptoms, which is seen as the body's way of coping with illness and as part of the healing process [8, 9]. According to homeopathic literature [5, 8, 9], the duration of aggravation depends on when the symptoms have started, the degree to which they have previously been suppressed or blocked, and the overall vitality or ability of an individual to heal. In acute conditions, aggravations will usually last for minutes and hours; in chronic conditions for days or weeks or, rarely, even months [8]. Aggravation must be distinguished from deterioration of the patient's illness according to the natural history of the disease and a worsening of symptoms due to the reduction of other medication [8, 10]. In a true aggravation, the patients will often give some indication of feeling better, either emotionally, mentally or generally, often with an increase in energy or improved sleep [11]. Aggravation is commonly observed by homeopaths and is usually estimated to occur at a frequency of 10–75% in clinical practice [6, 8, 9, 12, 13]. Adverse effects (AE) include all diseases or unwanted and/or harmful reactions appearing after taking medication, whether or not they may be connected to the actual treatment [14]. In 2000, Dantas and Rampes [15] evaluated the safety of homeopathic medicine in a systematic review where they critically appraised reports of AE published in England from 1970 to 1995. They concluded that homeopathy in high dilutions, prescribed by trained professionals, is in most cases safe and unlikely to produce severe AE. Dantas et al. [16] investigated the quality of homeopathy in homeopathic pathogenic trials in 2007. They also concluded that homeopathic medicine appears safe to use. However, it is difficult to draw definite conclusions due to low methodological quality of the included trials. Presently it is unclear when an initial aggravation becomes an AE, and when it ought to be reported as such [15]. To improve knowledge in this unexplored and important area of safety, we conducted 2 focus group interviews with 11 experienced Norwegian homeopaths. The aim of this study was to explore and compose criteria that may differentiate AE from homeopathic aggravations. The research question was: Is it possible to distinguish initial homeopathic aggravation from AE?

Material and Methods

Design

A qualitative approach was employed in this study using focus group interviews [17]. Qualitative studies may contribute to a better understanding and thorough knowledge of important issues in health and well-being,

Table 1. Sample characteristics

	n
Education	
Medical homeopaths	0
Non-medical homeopaths with at least 4 years homeopathic education	11
Full time private practice	11
Years of practice	
10–14	2
15–19	2
20–24	0
25–29	3
30–35	4
Classical homeopathy	11
Length of first consultation, min	
30	1
60	3
90	7
Additional therapies	
Classical acupuncture	5
Vitamins/minerals/herbs	4
Ear acupuncture	2
Foot reflexology	2
Nutritional therapy	3
Magnetic field therapy	1
Neurofeedback	1
Sex	
Female	6
Male	5

especially given a situation in which we have limited previous knowledge of our phenomenon of interest [17, 18]. In the field of CAM, the validity of qualitative methodology has been identified as fundamental to understand and describe the philosophical basis, key treatment components, and contextual frameworks of CAM modalities [19, 20]. We also used case analysis as theoretical approach to the empirical results. This study has been approved by the Regional Ethics Committee for Medical and Health Science in North Norway, and meets the standard of the Helsinki Declaration in its revised version of 1975 and its amendments of 1983, 1989 and 1996.

Participants

We looked for experienced classical homeopaths, since they are more likely to ask their patients about aggravation than complex homeopaths. The first author identified, with the help of the Norwegian Homeopathic Association (NHL), 13 experienced homeopaths who were invited to participate by e-mail. 6 women and 5 men accepted the invitation. Homeopaths in Norway receive their training in 4- or 5-year part-time programs offered by private colleges. The practitioners in this study were non-medical and have practiced classical homeopathy over a period of 10–32 years with an average of 24 years experience. They were based in 5 counties and worked in rural and inner city areas. The first consultation varied from 30 to 90 min, and the practitioners often offered their patients acupuncture as well as minerals, vitamins and herbs as additional therapies (table 1).

Focus Group Interviews

Focus group interviews were chosen, as this research method is particularly suited to the study of attitudes and experiences found around specific topics [17, 21, 22]. 2 interviews were performed in Oslo, Norway,

with 5 and 6 participants, respectively. The interviews took place in the NHL office. The interview guide was developed after systematic literature searches. The key words were 'aggravation', 'adverse effect', and 'homeopathy'. Seven databases were searched for articles, in which 27 randomized controlled trials (RCTs), 25 observational studies, and 7 surveys were identified. In addition, 12 articles were identified in the gray literature, and several philosophy books were found in a homeopathic library in Oslo. A theme-based interview was conducted using an open-ended and semi-structured technique [17], with T.S. as moderator and T.A. as observer. The main themes were homeopathic aggravation, AE, and criteria to distinguish between them. The focus groups were audiotaped and transcribed by T.S.

Data Analysis

We used qualitative content analysis to analyze text data focusing on the characteristics of language as means of communication with attention to the content or contextual meaning. The goal is to provide knowledge and understanding of the phenomena under study through a systematic classification process of coding and identifying themes [23]. The codes were defined before and during the data analysis. Hence, the coding was a mixed type, using elements from conventional and directed content analysis [23]. From this analysis, concepts and categories were developed.

Results

From the empirical analysis, 5 main themes emerged: aggravation, AE, proving, criteria, and highly sensitive persons.

Aggravation

The majority of the homeopaths claimed to have observed aggravations in 60–70% of their cases. They emphasized that 'as a practitioner you have to ask the patients about aggravation, if you don't, they will seldom tell you'. One of the homeopaths expressed: 'An aggravation is a positive reaction from the body to what remedy you have given. A change is initiated by systematic responses. First there is the reaction, and then comes the improvement. This all depends on how healthy you are'. Another explained: 'Common reactions such as headache and fatigue indicate positive response. These are superficial signs.' They described that many patients feel tired, get a headache, or a worsening of present symptoms after the remedy, which may continue for 1–3 days. A sense of well-being (sleeping better and feeling more energetic, mentally and emotionally stronger, and more balanced) often occurs soon after, which indicates that a curative process has started even though the present symptoms are worse. This process may continue for weeks, even months, and depends on how healthy a patient is. In contrast, if the reactions continue for more than 14 days without a feeling of well-being, it may be considered an AE. One homeopath said: 'Kent says that they (the patients) may experience a house cleaning effect. They may suffer from diarrhoea or perspire a lot.' Another explained: 'The level of reaction is to be more superficial compared to the person's initial problems. Let us put it this way, the person prefers the symptoms following the medication compared to those he had before. They need to be moved upwards and not

around.' The homeopaths referred to Hering's law of cure, who noted that the cure proceeds in reverse order from the most important organs to the least important organs, from the interior (viscera) to the surface (skin) and from the head to the limbs [8, 24]. It can be thought of as a centrifugal force throwing the illness out. It also reflects changes that flow through a person through energy stimulation caused by the remedies. The direction of the changes will indicate whether the prescription was therapeutic or not and may be an indicator of the patient's ability to heal. A woman expressed: 'Patients tell me that they reflect and dream more often. All in all they become more aware of themselves.' The impact of traumas on patients' lives was discussed: 'When meeting patients who have experienced traumas, I inform them that there will be reactions, often noticed in their dreams.' Another followed: 'People admit that they work the problems out through their dreams. They dream more often. It is normal. The dreams become more intense when the person improves mentally.' A woman concluded: 'In order to obtain improvement, it is important to get rid of it. Jung claims it is a cleansing, and afterwards they reach a deeper understanding of themselves.' These statements demonstrate that the decision-making in homeopathy relies on subtle information from the patients. One homeopath referred to the law of cure, which signals when a remedy has acted, when it continues to act, and what the direction of the action is. It also indicates whether and when a change of remedy or potency is needed. Therefore, the aggravation concept may be needed to control the healing process, which is clarified in this way: 'When I know what is happening, I am in control. Moreover, adjustments are made during the process.'

Adverse Effect

The homeopaths found it challenging to define homeopathic reactions as AE. Some of them found it difficult to define homeopathy according to an orthodox medicine paradigm. One woman expressed: 'To me this seems somewhat problematic, and I do not think that homeopathic remedies cause AE. AE are side effects caused by a substance given to the body, which causes symptoms similar to those of toxins. This is not the way homeopathy works in my world'. Another continued: 'Homeopathy does not cause a massive chemical burden which is the case with traditional medicines and drugs.' A third homeopath elaborated: 'My point is that the kind of AE which may be caused by homeopathic treatment are different from chemical/synthetic remedies, in that they do not poison or give new diseases that also need to be treated.' Moreover, one homeopath referred to Avogadro's number. This number ($6,023 \times 10^{23}$) gives the theoretical limit for when there is no longer any molecule left of the original substance. Mostly, homeopathic potencies are prescribed beyond Avogadro's number, therefore she said: 'Homeopathy is below Avogadro's number, and there is no poison in the substance that is given.' Accordingly, some home-

opaths found it unlikely that homeopathic medicines will produce AE, as these medicines are ultra-molecular and do not produce toxic effects. However, there were homeopaths who disagreed. A man said: 'In my opinion, there are lots of AE. I have had patients returning to me after many years, and have experienced worsening of eczema that never disappeared.' Another followed: 'Yes, it is. It is an undesirable effect of the medication. One could claim that it was due to an incorrect dose. Yes. It was an incorrect remedy, incorrect dose, and incorrect usage. Nevertheless, this does not prevent AE, an undesirable effect from occurring.' A man concluded: 'Vithoukas also claims that patients who are treated wrongly with homeopathic medicine loose energy. Their energy gets very bad. They get gradually worse the more they are treated wrongly. This is an AE. There are patients who suffer for years from negative reactions from homeopathic medication. If this is not an AE, I don't know what is. These are undesirable effects of the homeopathic medicine.' The discussion revealed that homeopathy may produce AE if the medicine is administered incorrectly. Over time, this may influence a patient's energy levels negatively. One of the homeopaths described an experience from her clinic: 'It is desired. However, it could get somewhat more intense than I had planned. I had a young boy who suffered from 'Sulphur eczema' (Sulphur is a homeopathic remedy often used to treat eczema) to whom I gave CM (very high potency). He ended up in hospital, but they were very nice. They gave him a bran bath, so he ended up having new skin all over his body. There was no sign of the eczema. He was just fine. However, this was quite a shocking experience. Again, the reaction is too intense, but on the other hand it is desired. And the parents coped very well.' She was supported by another woman: 'Parents worry very easily, as they do not want their child to suffer from eczema for a period. However, if the child is exposed to this, a gradual improvement will be experienced, and that is the intention. It is not an AE that is just present and will remain. After all, it has a purpose.' This homeopath admitted that the reaction was perhaps too intense but wanted, as the patient was cured from his illness at the end. In this context, the aggravation has a purpose. Moreover, another homeopath stated: 'AE may also be an initial aggravation resulting in reduced functional ability, even though this eventually turns out to be a success.' Another concluded: 'If the method is used incorrectly, we get undesirable, negative effects.' These statements demonstrate the disagreements among the homeopaths.

Proving

If a remedy is prescribed too frequently or a patient is highly sensitive, symptoms may occur which are produced by the remedy. A man said: 'Then, proving symptoms may occur. That is other symptoms than the patient already has. This may be characterized as an AE.' A man stated: 'I regard proving as an AE. Proving is an AE.' Most homeopaths in this study

regard 'proving' as an AE occurring due to the incorrect use of homeopathic medicines (proving is defined as an involuntary proving in a single patient and not in a single trial).

Criteria

The homeopaths found it difficult to find some criteria at first, but during the interview they started to reflect more deeply about how they make decisions regarding their patients and when to stop or continue the treatment. One of them expressed: 'The entire situation needs to be considered. Is it healthy or not? If the situation is healthy, I decide to continue'. Another stated: 'If the aggravation is worse than the person's initial level of symptoms, there is reason to be alarmed. Then there is an AE. This is not a curative reaction, and then the organism needs help to reach a better condition. Positive signs that this process has started should be seen. If not, the symptoms have just been moved.' In addition, a man expressed: 'If the reaction lasts for a very long period, it is not ideal'. Another continued: 'On my account, I must add that it's a matter of how certain I am in my choice of remedy, or do I have experience with similar situations?' A man explained: 'Overall observation. Usually patients come for a consultation and are followed up after a month. At a certain point in time (at the first follow-up visit) everything is recorded very carefully on all levels. This gives references which form a very good basis for assessing differences and dissimilarities in health.' A female elaborated: 'It is a matter of understanding the condition, to understand what goes on in the body, understand what happens to the patient and be able to assess this. Then try to find it (the remedy) according to where the patient is (level of health): which remedy covers the condition and where is the patient (the entire condition including physical and psychological symptoms). Then choose the appropriate dose accordingly. Then understand what prevents recovery. There may also be some obstacles to cure.'

Highly Sensitive Persons

A special patient group emerged from the discussion. A woman explained: 'I work at a clinic to which all of them come. These are the ones who are often sent to homeopaths. They are sensitive to everything. They barely tolerate daylight. They react so sensitively to this world, and they do not tolerate medicines, or light, or almost anything. They only have a much lower threshold. They react, and I often give them a lot less medicine than I give other patients.' Another woman explained: 'Then we get to the hypersensitive who have more AE than all the others put together. These are the patients who are complicated to treat. The patients are in a special category as we must identify them in order to help them. Hypersensitive people are generally very easily influenced. They react to all remedies they are given, whether the remedy is appropriate or not.' It is therefore important to identify this patient group in order to treat them correctly and avoid undesirable effects of the treatment.

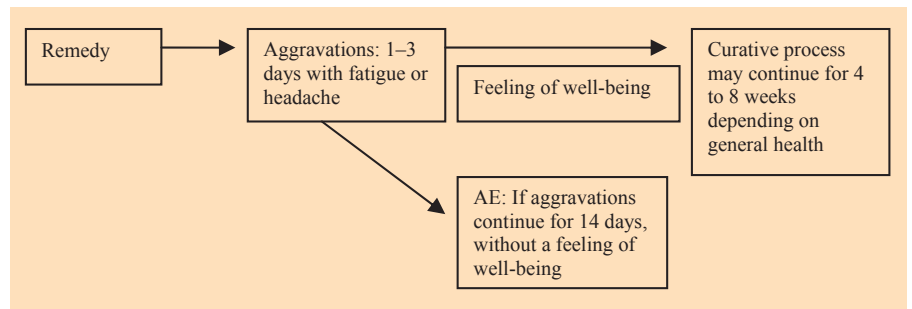


Fig. 1. Process of deciding whether a reaction is an aggravation or an adverse event (AE).

Discussion

This study provides novel qualitative insight into homeopaths' experience and handling of aggravations and AE. The participants in this study claimed that aggravation was wanted and purposeful. To decide whether the aggravation was part of a wanted reaction or not, all symptoms had to be recorded and observed carefully (fig. 1). In that respect, the time aspect and the patients' feeling of well-being were important. It also depended on how healthy the patients were and the direction of the change of the symptoms, which had to follow the principle of cure in order to be therapeutic. Further, it is important to understand what prevented recovery as there might have been obstacles to cure, which might have delayed the healing process [8, 10]. In 2003, Grabia and Ernst [13] published a systematic review to verify the existence of homeopathic aggravation by investigating how the phenomena were reported in RCTs. They found that 8 of 25 trials reported aggravations and 6 trials reported AE. They claimed that 'aggravations are clinically dramatic events that are difficult to miss and therefore should be reported in RCTs'. The lack of such reports led the authors to conclude that aggravations rarely happen or exist. Unlike Grabia and Ernst [13], we found that aggravations may be subtle and multi-faceted events from the homeopaths' point of view. Moreover, highly skilled homeopaths are required to identify and report aggravations. On the other hand, there seems to be a culture of not reporting aggravations as well as AE in homeopathic RCTs as demonstrated in the systematic review mentioned. Homeopaths argued that homeopathy was unlikely to produce any AE, because it is diluted beyond the number of Avogadro and does not cause massive chemical burden [25, 26]. On the other hand, several homeopaths claimed to have observed several cases of unwanted effects of the remedies. These contrasts demonstrate the problem of defining homeopathy, i.e. from a holistic and complex paradigm to an orthodox paradigm which is reductionist by nature and may risk losing sight of the whole [19]. We suggest that AE may be defined as 'an undesirable effect of a remedy' as it is pragmatic, flexible, and more in line with the holistic paradigm that the homeopaths represent. However, undesirable effects are in accordance with AE often used to

assess undesirable incidences in allopathic medicine, even though AE are exactly defined based on clinical speciality and the severity of the disease [27].

Highly Sensitive Persons

Highly sensitive persons hold a unique position as they are very sensitive to stimulations due to a highly receptive nervous system [28]. They may be more intuitive, have a greater awareness, and reflect more than others. Moreover, they are sensitive to medication and pain [8, 28]. Due to this sensitivity, they often visit homeopaths. However, to treat these patients according to homeopathic guidelines [11], it is absolutely necessary to recognize these patients in advance, as they require far less medication than others and are at risk of producing more undesirable effects than other patients. Furthermore, they are often difficult to cure.

Case Analysis

We used case analysis as a theoretical approach to our empirical study. Case analysis explains how homeopaths evaluate patients [8, 29], and explores the various steps in the treatment process. It includes: How to approach treatment for the patient; the patient's ability to heal; the extent of their illness; the level of their illness; and how they may respond to the treatment [19, 29]. This process of understanding how individual symptoms relate to the entire person is a distinctive mark for a holistic paradigm and is a generally accepted view in the CAM movement. We extracted 8 criteria categorized into 3 groups, representing various steps in a case analysis.

Case Management

When analyzing a case, the homeopath must decide whether the aggravation is part of a wanted reaction or not. If not, he/she must consider the aggravation as an undesirable effect. In this process, the following aspects must be considered: i) evaluate the entire observation, including the patient's general condition, social network, and obstacles to cure; ii) know the normal development of the disease (pathology) in order to evaluate the direction of the healing process; and iii) identify sensitive persons, as they react to all the remedies they are given, whether the remedy is appropriate or not.

Response to Treatment

Aggravation becomes an undesirable effect when i) the aggravation lasts for more than 3 days and the patient has not reached a feeling of well-being; and ii) the aggravation becomes worse than the person's initial symptoms. This indicates that the symptoms have moved from a superficial to a deeper level and shows deterioration of the case.

Treatment

The remedy may produce undesirable effects because i) the incorrect remedy has been administered; ii) the correct remedy has been administered but was given at an incorrect time or potency; iii) a close remedy match may have a worsening influence on the body. These findings demonstrate that homeopathy is a complex medical system with a network of components which can not be considered in isolation [30], and where the practitioner holds a unique position evaluating subtle patient information in order to separate aggravation from undesirable effect.

Methodological Aspects

The first author is a homeopath with 26 years of clinical experience. She knew that highly skilled homeopaths were needed to get solid information about aggravation. Therefore, the selection of the participants was purposeful and strategic [31, 32]. The discussion among the homeopaths about criteria demonstrated that the focus group approach was useful for answering the research question. The participants were experienced having a unique level of knowledge about aggravation. However, there may be reason to believe that less experienced homeopaths could hold other opinions than those revealed in this study. To obtain validity, the quotations were sent to the participants for verification [33, 34]. For clarification, T.S. phoned the participants and discussed ambiguous quotes [33]. During the interview, the participants were encouraged to speak their mind regardless of pressure from peers [17].

Information about AE and aggravation were explored and systematically collected in the literature review that formed the basis for the interviews. This strategy ensured saturation and theoretical transparency [31]. To obtain intercoding agreement, 2 independent researchers (T.S. and A.S.) coded the data, then jointly explored the data until a consensus was reached [23, 33]. This qualitative study has generated a hypothesis about safety issues. To get more information about aggravation and undesirable effects, it is important that re-

searchers report such events in their studies, which to this day seldom takes place. To improve this, more precise standards for reporting are needed. To obtain this, guidelines for adequately reported trials must be developed. A good example are the STRICTA guidelines for acupuncture trials. To obtain generalization [35, 36], a group of international homeopaths will be invited to participate in an email-based Delphi process [37, 38]. The experts will be asked to comment on our findings and if possible reach consensus about criteria that may distinguish aggravation from undesirable effect.

Implication for the Practice

We argue that this study may have implications for the practice, as our results highlight the need for inexperienced homeopaths to learn how to distinguish aggravation from undesirable effects; hence the 8 criteria will be useful for them. This may also become part of an education program where experienced homeopaths share their knowledge in order to avoid unnecessary suffering for patients.

Conclusion

This study rigorously explored homeopaths' views and experiences on aggravation and undesirable effects of the remedy. Furthermore, it has highlighted key elements that are unique and specific for homeopathic practice. Accordingly, it explored the complexity of evaluating the direction of the cure and how to decide whether a reaction is part of the healing process or not. The 8 criteria developed in this study may ensure patient safety and support therapists in identifying an 'undesirable effect of a remedy'.

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Disclosure Statement

The authors declare that they have no competing interest, and no financial interest exists.

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