'It's not my greengrocer, it's someone from the medical profession': A qualitative study regarding acceptability of deceptive and open-label placebo prescribing in France

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Received: 7 January 2022 | Accepted: 11 August 2022

DOI: 10.1111/bjhp.12624

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promoting excellence in psychology

ARTICLE

'It's not my greengrocer, it's someone from the medical profession': A qualitative study regarding acceptability of deceptive and open-label placebo prescribing in France

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Funding information
Swiss National Science Foundation (SNSF), Grant/Award Number: PZ00P1_201972

Abstract

Objectives: To explore participants' views regarding clinical use of deceptive placebo (DP) and open-label placebo (OLP) treatments.

Design: Qualitative thematic analysis.

Methods: We conducted eight semi-structured interviews with healthy participants in an experimental trial comparing the efficacy of OLP and DP (Clinical trials n°NCT03934138). Interviewees' opinions were solicited following administration of placebos during the trial. Interviews were analysed using data-driven analysis.

Results: We identified three themes. First, participants considered trust central in judging a placebo treatment to be acceptable. They expressed the importance of an implicit trust both in their health care professionals' (HCPs') competency as well as in the profession at large. A second theme was the perception of how placebo treatments might solve health problems. Acceptability of both types of placebo treatments was dependent on the perception patients had about the treatment solving their problem and/or doubts regarding the effectiveness of placebos The third theme encompassed perceived risks associated with placebo prescribing. Some

comments viewed placebos positively as facilitating reduced medication intake. However, participants also identified the potential of placebos to generate adverse side effects.

Conclusions: Treatment acceptability by patients is a prerequisite, alongside effectiveness, to harness OLPs in clinical care. Our study identified the importance of trust in HCPs prescribing placebos, the clinical effectiveness of placebos and the potential risks of these interventions in assessing their acceptability. Future research is needed to explore the contexts in which placebos might be used, and how best to communicate information about placebo interventions.

KEYWORDS

ethics, open-label, patients' attitude, placebo, placebo attitudes

Statement of contribution

What is already known?

- In clinical settings, placebos are widely used.
- Deceptive placebo (DP) prescribing raises specific ethical concerns.
- Honestly prescribed – or so-called 'Open-Label Placebos' (OLPs) may have the potentially to harness beneficial placebo effects while also respecting patient autonomy.
- The premise that OLPs will be less infringing on patient autonomy, however, does not mean patients will consider them acceptable.
- Aside from establishing the effectiveness of OLPs to harness placebo effects, it is also important to investigate whether patients find OLPs acceptable.
- In some previous studies, participants have been requested to offer their opinions which were not informed nor based on experience with placebos.
- In this study, we interviewed participants after disclosure about this intervention and after they had experienced either DP or OLP in a clinical trial setting.

What does this study add?

- Participants considered trust central in judging a placebo treatment to be acceptable. Trust was affected differently by DPs and OLPs.
- Intervention preference was far from unanimous, suggesting acceptability of placebos may be patient-dependent.
- This is the first study, to explore the acceptability of DP and OLP in France.

INTRODUCTION

Placebo interventions are used in clinical research to evaluate a treatment's specific efficacy (Ernst & Resch, 1995); however, clinical uses also exist. In clinical settings, placebo use may even be quite common (Fässler et al., 2010; Linde et al., 2018). A recent meta-analysis (Linde et al., 2018) showed usage among general practitioners in the previous year ranged from 46% to 95% with a pooled estimate of 76% (95% CI: 61%–86%).

Despite these findings, it should also be emphasized that many disagreements persist with respect to defining placebo concepts (Blease & Annoni, 2019). For example, Miller suggests restricting the definition of placebo effects to situations where intentional inert interventions are used (Miller, 2018). Benedetti appears to consider a larger scope for defining placebo effects. He writes that the placebo effect is the difference of effect between an expected and unexpected treatment even when no placebo treatment has been given (Benedetti, 2020). This was illustrated in a well-known experience comparing open and hidden administration of morphine injections (Benedetti et al., 2011). Other scholars suggest abandoning the term of placebo altogether. Alternatives have been suggested such as Moerman's 'meaning response' focusing on social and cultural significance of treatments where the *meaning response* is defined as 'the psychological and physiological effect of meaning in the origins or treatment of illness' (Moerman & Jonas, 2002). Howick in his recently proposed revision of Grunbaüm's model attempts to co-define the terms 'placebo' and 'placebo effects' and describes placebos largely as treatments whose effects are not based on characteristic features of treatments but rather on incidental factors (Grünbaum, 1986; Howick, 2017). For example, the characteristic features of amoxicillin are its antibiotic constituent; the incidental features include its coloration, taste, bulking agent, branding and price. Howick proposed that, 'a treatment process is a [generic] placebo when none of the characteristic treatment factors C are effective… in patients X for D'; he interprets 'characteristic features' as a feature of treatments that '(1) is not expectancy that a treatment is effective; and (2) that has an incremental benefit on the target disorder over a legitimate placebo control' (Howick, 2017). According to Howick, a placebo effect is, 'either (a) a remedial effect produced by the incidental features of some treatment… or (b) any effect of a generic placebo' (Howick, 2017). While Turner argues the terms 'placebo' and 'placebo effects' may ultimately prove not to be analytically useful, Blease argues that the terms should be independently defined. In clinical settings the term placebo may be variously used to refer to treatments that are prescribed, which have no known effects other than potential for placebo effects, or which are used to placate patients for whom no treatment is available (Blease, 2019; Blease & Annoni, 2019). Blease also argues scientific advances can legitimately be described as constituting a mature 'placebo effect paradigm' replete with progress and empirical growth (Blease, 2018).

Conceptual disagreements are not merely philosophical, but carry ethical and practical consequences for the use of placebos, and how to adequately interpret the size of placebo effects (Blease & Annoni, 2019; Hardman et al., 2020; Turner, 2011). Notwithstanding disagreements, many researchers in the field of placebo studies consider placebo effects to be genuine psychobiological effects that engage perceptual and cognitive processes to elicit therapeutic benefits (Kaptchuk & Miller, 2015). To this end, it is variously proposed that the placebo effect might be usefully harnessed in clinical settings. This may be achieved via particular vigilance to contextual factors that might elicit placebo effects in everyday care (Di Blasi et al., 2001). Additionally, strengthening communication and therapeutic alliance in clinical settings may harness improved outcomes (Kelley et al., 2014; Street et al., 2009), including via placebo effects. As Locher and colleagues propose, the ritual of prescribing a pill could also be conducted in a deliberate manner (Locher et al., 2019). Lastly, non-verbal communicating and artefacts in the context of care could elicit placebo effects (Bernstein, Locher, Kube, et al., 2020; Howe et al., 2019).

Although some patients might potentially benefit from placebo effects arising from placebo use, deceptive placebo (DP) prescribing invites ethical concerns. For one, deception in clinical practice may violate the patient's autonomy with regard to making informed decisions about the treatment. Potential harm to the therapeutic relationship, as well as in general trust towards healthcare professionals (HCPs), is also a concern. At the same time, health ethicists are not in agreement (Foddy, 2009) with some arguing that the benefits outweigh the risks, or that deceptive placebo prescribing does not infringe on morally important forms of patient autonomy.

Treatments that rely on the placebo effect while being open and honest with patients regarding the inert nature of the treatment, might present a way to respect these ethical dilemmas (Blease et al., 2016). Such interventions, called open-label placebos (OLPs) depend on the rationale given before administration and can take several different modalities; from an inert pill, to a cream or taping. It is proposed that OLPs optimize treatment response while respecting patient autonomy. Although deception was

previously believed to be crucial to obtain placebo effects, a growing body of research suggests that this might not be necessary (Charlesworth et al., 2017; von Wernsdorff et al., 2021). In multiple studies, OLPs have been compared to no treatment. A first meta-analysis (Charlesworth et al., 2017) in 2017 found a standardized mean difference of .88 (95% CI: .62, 1.14) and a more recent meta-analysis (von Wernsdorff et al., 2021) showed a standard mean difference of .72 (95% CI: .39, 1.05). However, studies regarding OLP are still nascent and suffer from methodological difficulties regarding blinding for example (Blease et al., 2019). It is also unclear if and how the results found in experimental and clinical trials translate to routine clinical practice (Miller, 2018). To date, the small number of studies, their heterogeneity and the risk of bias calls for caution when drawing conclusions on efficacy. While effectiveness is being evaluated, the premise that these treatments will be less of a hindrance on patient autonomy does not mean patients will consider them acceptable. Perhaps most importantly, it is necessary to probe whether patients themselves consider deceptive placebos to be unethical (Bishop et al., 2014). However, aside from the transparency in its administration, there is little information today about the information given or not to the patient during the administration of an OLP (Heiss et al., 2021; von Wernsdorff et al., 2021), or whether patients find these treatments acceptable (Blease, 2019).

A limited body of research has explored whether patients consider deceptive placebos to be ethical. Fässler et al. found that HCPs thought DP treatments to be less acceptable than patients did (Fässler et al., 2011). As such, patients were seven times more likely than the physicians thought to accept a placebo intervention if it would allow them to gain a therapeutic advantage through the placebo effect.

Several recent studies included patients when considering DP's acceptability criteria (Bishop et al., 2014; Fässler et al., 2011; Hammami et al., 2019; Köteles & Ferentzi, 2012; Ortiz et al., 2016; Pugh et al., 2016). Surveys and focus group studies reveal that acceptability is influenced by expected benefits (Bishop et al., 2014; Fässler et al., 2011; Hammami et al., 2019) as well as lack of harm (Ortiz et al., 2016). It also seems the closer the information was to a lie rather than indirect information (Marsili, 2014), the less acceptable treatments were considered to be (Pugh et al., 2016). Some patients even consider benefits and therapist intentions to be more important than deception (Hammami et al., 2019). These findings might be said to describe a pragmatic view of placebo interventions (Köteles & Ferentzi, 2012). However, such views are not ubiquitously held. A subgroup of patients appear to place more importance on trust and truthfulness and, therefore, value honesty above all else (Bishop et al., 2014).

Regarding OLPs, only a few theoretical studies so far have looked at treatment acceptability. These studies suggest OLPs are ethically valid treatments (Blease et al., 2016). Fewer studies included patients such as Haas et al.'s study (Haas et al., 2021) comparing DP and OLP treatment acceptability through online vignettes. These results showed a higher acceptability towards DP than OLP among lay people. This was correlated to a higher expectancy towards DP rather than OLP (Haas et al., 2021). However, previous studies included participants requesting them to offer opinions not informed nor based on experience. This is one of the major difficulties when including patients into studies regarding OLP acceptability. Even more so as OLP treatments are not widely used; and therefore, only a few people have experienced them. Similarly, physicians sometimes consider OLP to be disrespectful to patients and at risk of offending them (Bernstein, Locher, Stewart-Ferrer, et al., 2020). One qualitative study interviewed healthy participants to explore OLP usability but with an aim less focused on acceptability rather than on the plausibility of the treatment rationale (Locher et al., 2021). This study looked at lay people's attitudes towards OLP treatments after use focused on the rationale rather than the acceptability of the treatment (Locher et al., 2021) without informing participants of the existence of OLP treatments in the non-OLP groups. Again, however, there are documented discrepancies in how the information is communicated to participants during the administration of OLPs in clinical trials (Heiss et al., 2021; von Wernsdorff et al., 2021). These differences could influence the acceptability of the intervention.

The objective of this qualitative thematic analysis is to build on this body of research into patients' views about DPs and OLPs. We interviewed participants after an education on these interventions and after they had experienced one or the other in a clinical trial setting. To our knowledge, this is the first

TABLE 1 Topics and questions in semi-structured interviews

Topic	Description	Initial question	Example prompts
Open-label placebo use	These topics looked at the attitude participants had regarding open-label or deceptive placebo treatments, whether or not they would deem their use acceptable or not, how this would impact the way they judge their healthcare professional and what factors drive their opinion	'Imagine you go to see a healthcare professional. He or she suggests an open-label placebo treatment for pain management after explaining that it is a placebo treatment, what we know about it and how it works. How would you judge this situation?'	• Could you explain what would make this situation more/less acceptable to you? • Could you describe a situation where you would/would not accept this intervention? • How would you feel if you were in this situation? • How would this situation impact your relationship with your HCPs?
Deceptive placebo use		'Imagine you go to see a healthcare professional. He or she suggests a deceptive placebo (previously explained) for pain management. From an outside perspective, meaning you are aware of the situation, how would you judge this situation?'	• Could you explain what would make this situation more/less acceptable to you? • Could you describe a situation where you would/would not accept this intervention? • How would you feel if you were in this situation? • If you were to learn about this, how would this impact your relationship with your HCPs?
Treatment preference	This topic looks at which treatment is preferred in a given situation	'Given everything we have discussed, regardless of the conditions, which treatment between OLP and DP would you prefer to take for pain management?'	• Could you develop your answer further? • What drove you to choose this view?

study, to explore acceptability of DP and OLP among lay participants in France. It is also one of the first to interview participants after having experienced either of these treatments.

MATERIALS AND METHODS

Study design and participants

The qualitative study was nested in a non-inferiority randomized trial aimed at comparing the efficacy of DP and OLP on experimental pain with healthy participants (Druart et al., 2020). The study took place at the University of Grenoble and was approved by the national ethics committee (2017-A01643-50). All research participants gave informed consent. In this clinical trial, 60 subjects were randomized into two groups: one received a DP and the other received an OLP. Both groups also underwent a no-treatment (NT) condition in which the pain stimulus was delivered with no treatment. The method used in the clinical trial as well as its registration information are detailed in a separate paper (Druart et al., 2020).

During the trial, participants from the OLP group watched a video (bit.ly/Placethic-Video) aimed at explaining the mechanisms of placebo on pain relief before receiving their treatment. A video on a completely different subject was viewed by the DP group (https://youtu.be/WQVYWUsrfbk). Before interviews, the DP group was given the time to watch the video the OLP group had seen during the trial. This allowed for both groups to be offered the same information about OLPs and simulate the setting in which an OLP could be proposed to a patient (i.e. after information regarding OLP).

Qualitative interviews all took place immediately afterwards. This allowed us to explore the views of participants immediately after experiencing an OLP or DP treatment.

Data collection

Data were collected through face-to-face eight semi-structured interviews lasting 30–40 min following common-practice methodological recommendations (Braun & Clarke, 2019). We aimed to recruit four to eight participants in our study in line with similar studies in placebo research (Bishop et al., 2012). Our qualitative thematic analysis was exploratory, and we did not aim for data saturation as the concept is not always desired (Braun & Clarke, 2019). The number of participants was also limited due to logistical constraints in scheduling interviews among members of the research team. We invited eight participants who enrolled in the trial to participate in interviews. All persons approached accepted. Although participation in the clinical trial was compensated by 20€, participants did not receive extra compensation for their time in the interviews.

The interviews were conducted by O.V. The interviewer started by debriefing participants about the clinical study. Then, the aim of the interview ('We want to understand what you think about placebo treatments') and its process ('The interview will be recorded for transcription purposes however anything you say will be anonymous and confidential') were explained. All participants of the DP group were invited to watch the video about the OLP approach before the interview.

The interviews addressed three topics (described in detail in Table 1). The order in which the topics of OLP and DP treatments were discussed was chosen randomly for each participant. This was done to minimize overrepresentation of one treatment over the other. Prompts and probes were used to ensure questions were answered as deeply as possible (see Table 1).

Data analysis

Thematic analysis was undertaken using a data-driven (or inductive) analysis (Braun & Clarke, 2006, 2013) and comprising five steps: pre-analysis, coding, categorization, refining and interpreting. (1)

Pre-analysis consisted of the transcription of the interviews by O.V. and proof-read by L.D. to increase reliability of the transcription. Next, O.V. and L.D. familiarized themselves the material by reading through the transcripts several times. (2) Coding was then conducted by L.D. and O.V. where '[nodes of meaning]' (Bardin, 2013) were identified and coded for presence and direction. During this phase, analysts can choose between a semantic (words used) or latent (meaning of text) approach. The latter was chosen in this study to allow for more in-depth understanding(Coolican, 2017). When discrepancies were found between coding, both analysts discussed and, if needed, a third author (N.P.) weighed in to resolve disagreements. (3) Next, via a process of higher-order categorization we sorted the codes into themes with the help of a thematic map. This was undertaken by O.V. and L.D. (4) The themes were then refined by all authors. All sample quotes were translated into English by L.D. and O.V.

The online software was used (https://www.qcamap.org/) to assist with coding the data.

RESULTS

Interviews were conducted with eight people (three males and five females) of the 60 participants of the trial; ages of participants varied between 19 and 34 years (see Table 2). Among the participants, four interviewees received a DP in the experimental trial and four received an OLP.

After analysis, we coded 92 categories (39 regarding OLP, 39 regarding DP and 14 regarding placebo effects in general). These categories were organized into three main themes, which were further subdivided into subthemes (see Table 3).

Trust in HCPs and placebo prescribing

Implicit trust in HCPs

Many participants signalled implicit trust in their HCPs as influencing whether they considered placebo treatments acceptable. Among these comments, some participants described their trust in HCPs' competency, for example: 'if he prescribes it to me I guess it's the best thing to take so I'm glad he prescribes it to me' [A]; and also '[I]f he is convinced it is because he also has a scientific background, I suppose it is his role also to have made sure that the effectiveness was proven' [G].

Some participants implied trusting the fact it's an HCP's function to treat them; for example:

> the fact that it is recommended by eh, well, my doctor or my physiotherapist it is someone who is knowledgeable.
>
> [D]

TABLE 2 Sample description

Subject	Trial group	Gender	Age	Occupation	Interview order
A	OLP	Male	21	Student	OLP then DP
B	DP	Male	24	Unemployed	OLP then DP
C	OLP	Female	21	Student	DP then OLP
D	OLP	Female	28	Employed	DP then OLP
E	DP	Female	27	Employed	OLP then DP
F	DP	Female	19	Student	OLP then DP
G	DP	Male	34	Manager	DP then OLP
H	OLP	Female	28	Manager	DP then OLP

TABLE 3 List of themes

Trust in HCPs and placebo prescribing	Implicit trust in HCPs
	Potential to breach trust
	Trust and the use of OLPs
Perception about solving the clinical problem	Effectiveness matters most
	Treating physical causes
	Doubts about potency of the effect
	Other treatment options
Perceived risks associated with placebos	Avoid risks of medications
	Side effects of placebo
	Balancing benefits with risks

> in the end it's the practitioner who chooses according to the results that there are in the studies. I mean it's his job to choose the best option possible. It's not as if we went to the garage and we had a quote and that we had to choose a quote… He won't offer you a choice between an open placebo or a closed placebo and say which one do you take? No, but it is up to him to decide according to his knowledge.
>
> [G]

> [I]t's not my greengrocer [prescribing the treatment], it's someone from the medical profession, it's ok […] If the doctor thinks that [DP] can solve the problem as the main treatment and that there is no need for another treatment I will say yes.
>
> [D]

This trust went further for some patients who saw it as justification for a more paternalistic approach in the therapeutic relationship: "in any case when we are not a doctor, we listen to what we are told to do." [H]

Potential to breach trust

Some participants described use of DPs as a breach of trust; for example: 'you trust someone and the person does not tell you everything. Even though it is your body, it is your injury, it is your pain, it is you who takes it, it is your side effects… it's easy to be on the doctor's side but since you are the patient uh…. I would take it badly' [F]. This was especially true if the trust was not already established in the therapeutic relationship: 'If with the practitioner we are already lacking a little in trust, it would be a kind of betrayal' [C].

Other participants voiced their wish to be included in the decision process concerning them, and described breaches of trust following DP administration as decisive in their future relationship with their clinician; for example,

> I would never see him again […] saying: Why didn't you tell me? I would listen to these explanations. But, after that, I do not think I will return. The trust would have died.
>
> [F]

> I'm going to be a little mad and I'm not going to go back to see him. It's going to offend me actually. […] Because I'm very trusting, I trust [my HCPs] etc., and I think that everything depends on trust and not on lies. Either we talk about it and we make the decision together or..[not]. […] Frankly unless I am in a coma and not conscious and that they can lie to me without me having a reaction; but otherwise no I do not want to be lied to, no […]. I think I will not trust him anymore and change [HCP].
>
> [E]

Some participants questioned the intent of HCPs to use placebos and signalled the potential to diminish trust of these treatments. For example, 'I think he/she shouldn't do that just to get rid of you and make money off you otherwise it would be a shame' [G]. Again, this questioning about intent in relation to trust was, for some participants, an important factor in deciding whether or not the treatment was acceptable:

> What are the objectives? If their goal is just to avoid paying or doing something that takes them longer or if it's a thing that benefits them and not you well all the sudden it's sad. But if it's always with the moral goal of helping you get better, well in that case I'm always ok.
>
> [B]

Trust and the use of OLPs

Some participants suggested OLPs might enhance trust in the HCP; for example: 'if I was logical enough I would say I prefer open, the advantage is that we are perhaps more integrated into the thing, it is true that it is more appealing and gives greater trust' [G]. In comparison with DPs, participants suggested that OLPs could help protect trust in HCPs; for example:

> Suggesting an open placebo like: 'ok, I suggest this treatment, I give my opinion, yes or no' where I can choose. […] At least there's honesty, we both know what we are engaged in and in the end it is still my body and I think that there's no justification to lie about what we are giving me.
>
> [E]

> [T]he advantage is that we are perhaps more integrated into the [process]. It is true that it is more desirable, gives greater confidence… it's sure that if she/he explains well, the practitioner explains everything well, and then tells us "we do it like that" and everyone is aware of everything, there is not this impression of lying a little bit.
>
> [G]

According to multiple comments, how OLPs were described could have potential to either strengthen or strain trust; for example:

> [it is] how [the practitioner] sells his/her thing.
>
> [B]

> I have to feel that I have free will. That I don't feel manipulated.
>
> [F]

> [This can be done]…by telling me that there are studies. In any case they showed me that there were studies that proved it so I have a little desire to believe a little bit. If he explains to me and he manages to demonstrate that there is an efficiency.
>
> [G]

One participant indicated that overselling OLPs could undermine trust in the HCP: 'He has to explain it objectively enough so that I can make up my mind rather than trying to sell me the thing like a shaman there' [F].

Other participants considered trust in their prior relationship with their HCP as crucial to whether they considered OLPs acceptable:

> I will give more importance to the advice of someone that has already helped me.
>
> [B]

> [If] this is the first time I see the person I'm going to be skeptical.
>
> [F]

> [I]t depends on which health professional offers me this. If it's someone I trust or if it's someone I'm a little suspicious of.
>
> [H]

Perceptions about solving the clinical problem

Effectiveness matters most

Some participants were explicit in emphasizing effectiveness as the most important factor in deciding if a placebo treatment was acceptable; for example:

> the goal of taking a treatment is that it works.
>
> [G]

> if there is an effectiveness it will not bother me ethically that I am not told the truth […] if you go to the doctor, it is to have a result no matter how you get there.
>
> [H]

> if I encounter pain and if it allows me to suffer less I am open to everything.
>
> [D]

Other participants offered more nuanced perspectives, even while suggesting effectiveness was a leading concern; for example: 'it depends if […] it is beneficial for me and if I was deceived on part of the treatment that had no negative impact on me, that just had the aim of being positive. In which case it's just beneficial' [B]. Relatedly, some participants were focused on whether the HCP considered the treatment effective: 'if he thinks it can relieve me I don't see any problem. […] if it's to do tests, I'm not ok' [D].

One participant noted that a placebo treatment would not be acceptable, on the grounds that HCPs have the power to offer something more potent:

> [B]y default when I have pain I will try to work with placebos by myself and if I go to see the doctor it is that I am at a stage where I want a solution.
>
> [B]

Treating physical causes

Some comments suggested placebo treatments were perceived as useful for treating symptoms, but not the cause of the health problem:

> it has an efficiency but if I understood correctly it generates endorphins and endorphins do not solve the problem. It makes the pain more bearable. Whereas if I go to see the doctor, it's that I want to solve the problem.
>
> [B]

It was important to some respondents that the cause of the symptomatology be treated before considering a placebo treatment; for example:

> I would not accept being given false morphine. Once I am treated with a cast for example, it does not bother me. All the same, if I have a serious disease like cancer and that my cancer is not treated, it would bother me. But if I am given a placebo for the pain related to cancer [it's ok].
>
> [H]

> if I tell him I have tendonitis and he tells me to take a placebo I will tell him ok for pain management but it will not change that I have tendonitis.
>
> [B]

Relatedly, one participant noted that the placebo effect could only have a psychological effect on symptoms: 'the principle of placebo is that, I mean… It's empty. It's psychological.' [F].

Doubts about potency of the effect

Regardless of whether participants were offered OLP or DP, a number of comments suggested placebos were perceived as less potent than drugs: for example: 'If it works, all the better. If it doesn't work I would tell [the HCP] I want something stronger' [A]. Some participants also doubted the clinical relevance of placebos saying '[I'd say] that me, I actually want to be treated' [C] or even 'I am skeptical. […] I will not be in the right mode. Actually, I think it will not work because I would say: anyway it's psychological' [F].

Such views led one participant having received a DP during the trial to question the legitimacy of their perceived improvement during the experiment: 'Frankly, I really felt a difference so uh… but I think it is not related to the fact I took the cream' [E]. In contrast, when the pain in the experiment was not completely remedied by the placebo treatment, one participant that had received a OLP during the trial felt 'a little embarrassed, […] I had a small disappointment that it was not as huge as what I had been told. I thought I would be almost pain free' [H].

Other treatment options

Some comments also indicated placebo treatments would be more acceptable in scenarios where no other treatment options were available: 'if you are in therapeutic failure, if there is no other treatment or if the treatment is not effective… Well yes anyway might as well try' [E] or 'I will accept even more because it may be the only option that will help me' [D]. One participant hinted that not only clinical effectiveness but conventionality in offering a mainstream treatment was also important: 'if there is a more obvious solution to the problem, well I will find it a pity that he does not suggest it' [B].

Perceived risks associated with placebos

Avoid risks of medications

Participants identified avoidance of medication intake as one advantage of placebos over other treatments; for example: 'So I think it's good at first to use a placebo, to avoid drug substances […] not necessarily use anti-inflammatory drugs' [C]. This benefit was especially cited in relation to potential for medication side effects, for example: 'less risks of side effects than a drug' [G]. However, other participants were more nuanced in their comments, and still perceived the necessity of medications, for example: '[I]f it can limit the amount of drugs I take it's cool but I also don't want it to take care of everything' [D].

It was also apparent that placebos were seen as less invasive than medications, for example: 'It's a little less substance that's not supposed to be in your body I would say. If there is a placebo that can replace so much the better' [A].

Side effects of placebos

However, participants also considered the potential side effects of the placebo treatment itself, for example: 'as long as there are no negative repercussions for the patient' [G]. Pain was a commonly identified potential side-effect of placebos:

> if I treat one pain to have another pain, suddenly I'll question it a little.
>
> [D]

> Too many side effects that are more disabling than my pain in itself because suddenly it would not be good and if I suffer more afterwards.
>
> [D]

Relatedly, the administration of the placebo treatment was cited as a potential source of side effects:

> There is the method of administration of the OLP that should not be too painful.
>
> [H]

> I will have more concern about invasive [placebo] surgery.
>
> [G]

Notably, for one participant, placebos were perceived as less invasive than medication but also having potential for side effects: 'We can try because if it is less intrusive at the level of the body and as long as the pain can be bearable' [E].

Balancing benefits with risks

Another concern was that the benefits should be balanced against the risks when it comes to decisions about placebos versus other treatments, for example: '[I]t's always the same comparison between the benefits and then the risks you take' [G].

The benefit–risk ratio implied weighing up multiple different factors: 'if there are possible side effects or, I don't know, anything that can change something or the disease, […] or, I don't know, if for example the disease absolutely must be treated now I prefer to have something where I am already convinced of the effectiveness' [A]. Several participants reported elements of the clinical situation that they

believed would influence acceptability of a placebo treatment including the chronicity and the intensity of pain, the seriousness of the pathology and the urgency of a treatment. For example, to illustrate the impact of the chronicity of pain: 'if it is a pain even that has been there for a long time but is sustainable, I think that precisely it is almost more logical if it has been going on for a long time to use a placebo' [A]. For other participants, chronicity was a deterrent towards placebo treatments: 'if [the pain] lasts for a very long time, I will be less likely to accept [the placebo]' [B].

One participant identified the risk of opting for a placebo treatment if it did not improve the situation thereby forfeiting other, potentially more effective, options: 'I would tell myself that I do not want to take the risk that it does not have the effect that I want it to' [H].

DISCUSSION

This study aimed to explore lay people's viewpoints on deceptive and open-label placebo treatments. Undertaking interviews and qualitative thematic analysis, we identified three overarching themes related to both placebo interventions. First, our participants considered trust central in judging placebo treatments acceptable. Participants expressed the importance of implicit trust both in their HCPs' competency, as well as in what it meant to be an HCP, and related the importance of trust in acceptability of placebos. A second major theme was the perception of how the treatment could solve presenting health problems. Our results found acceptability of both types of placebo treatments was dependent on the perception patients had about the treatment solving their problem as well as the doubts they had regarding the effectiveness of placebo treatments. The third major theme encompassed perceived risks associated with placebo prescribing. Some comments positively endorsed placebos as facilitating reduced medication intake. However, participants also identified the potential of placebo treatments to generate potentially adverse side effects. Participants expressed the need for risks to be balanced with regards to potential benefits of placebos.

Comparing our results to the current literature reveals some similarities to previous studies. Expected benefits and perceived risks were major themes highlighted in other qualitative research about DP (Bishop et al., 2014; Fässler et al., 2011; Hammami et al., 2019; Ortiz et al., 2016). These themes are also present in physician views regarding the prescription of placebo treatments (Bliamptis & Barnhill, 2021). We also found other participant responses previously identified in the literature. Some participants preferred effectiveness over honesty (Köteles & Ferentzi, 2012) whereas others value honesty over all else (Bishop et al., 2014). However, beyond currently published qualitative studies, but in line with published ethical analyses (Annoni, 2018; Annoni & Miller, 2014), our findings added a novel perspective by revealing an important focus on trust with regard to placebo treatments. Our results also hinted that OLPs and DPs impacted trust differently. DPs were seen by some participants as a breach of trust and a potential threat to the therapeutic relationship bringing doubts regarding the intent of the HCP. In contrast, prior trust in the HCP and plausibility of the treatment rationale appeared to be regarded by our participants as important for OLP acceptability.

Interestingly, in contrast with other qualitative studies, our participants identified the potential for side effects of placebo treatments. This could be due to: a misunderstanding of the inert medical nature of placebo treatments, anticipation of potential nocebo effects or even in some cases suggestions that side effects could be due to the administration method of the placebo intervention (sham surgery for example). Alternatively, participants may have interpreted this to mean stigmatization or other negative psychological effects prompted by the administration of placebos (Blease, 2019; Blease et al., 2019; Specker Sullivan, 2021). Another point of interest is that placebo definitions from the public may influence their views of placebo and, therefore, acceptability (Hardman et al., 2019). This seemed to be the case in our study. For example, people viewing the placebo effect as treating only imaginary affections were less likely to find it acceptable.

It is important to reflect whether choosing the preferred treatment modality is linked to what is expected of an HCP and more largely of the preferred model of patient-clinician partnership. Our

results suggest different representations of what participants expected of their HCPs. Some expected to be included in the decision-making process (adopting a so-called patient-centred model) and others expected the HCP to know what was best and act upon it (adopting a more paternalistic model of care). In our data, there were different patient profiles. Some patients seemed to prioritize treatment efficacy over autonomy and others appeared to favour autonomy even if with a loss of efficacy. Similar studies on placebo acceptability have found such stances labelling one a 'consequentialist' point of view and another an 'autonomy respecting' point of view (Bishop et al., 2014). Although our study was limited, placebo preference does not appear to be unanimous. It may be that the answer to whether an OLP is more acceptable than DP is patient-dependent, which could also be true when comparing acceptability of placebos with conventional treatments. Although OLPs were initially thought and tested as ethically more acceptable interventions compared with deceptive placebos, our results seem to hint participants were not in agreement with respect to the ethical acceptability of OLPs. The question of comparing DP to OLP regarding efficacy is even more relevant with this in mind and is currently under investigation in published and undergoing trials (Druart et al., 2020; Locher et al., 2017).

We also note, among participants, placebo treatments appeared to prompt common acceptability criteria that might arise with any other clinical treatment: Sekhon et al. defined acceptability as 'a multifaceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention' (Sekhon et al., 2017). Our results hint at the seven dimensions comprising acceptability: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy (Sekhon et al., 2017). This leads us to consider that placebo treatments could have similar levers influencing treatment acceptability as any other treatment.

Strengths and limitations

This study has several strengths and limitations. First, our trial is one of the few studies to date that has been conducted on placebo acceptability in France. Treatment acceptability can vary depending on socio-cultural context (Bhugra & Ventriglio, 2015; Ventriglio et al., 2018) and this is worth highlighting. This is also one of the few studies, to our knowledge including lay perspectives about treatment acceptability both for DP and OLP. In addition, few studies have conducted qualitative research into placebo interventions in a pragmatic setting: participants actually experienced the intervention allowing them to give a retrospective (i.e. experienced) feedback on the placebo to which they were allocated and a prospective (i.e. anticipated) view about the other placebo modality (Sekhon et al., 2017). Even fewer studies have compared the acceptability of DP and OLP. To the extent of our knowledge only one other study had these similar strengths (Locher et al., 2021). Few studies discussed the variety of administration of placebo interventions ranging from an inert pill to manual therapy, surgery or other non-pharmacological interventions. Our patients also benefited from a standardized information capsule, although not validated by a separate study, provided during the trial or before the interview depending on the group to which they were randomized. Minimal information was given to participants following the video as researchers' conceptual views on placebos may heavily influence the answers given by participants later on. This is especially true regarding placebos and the multiple conceptual differences that exist surrounding them (Hardman et al., 2020).

Our study also has limitations. The sample size was restricted. Although the concept of data saturation is not always a desired goal (Braun & Clarke, 2019), and our survey was exploratory in nature, we note it was not clear from our interviews whether we achieved data saturation. Inferences on the basis of the sample are further limited because our subjects were healthy and mainly young. Acceptability modalities could vary in other settings or populations. The clinical trial setting, although allowing a pragmatic study, invited other methodological shortcomings. Although our participants experienced the treatments, this is still research conducted in an experimental setting and it is unclear if and whether these findings translate to a clinical context. For example, there is reason to believe that experimental

pain is different to the experience of chronic pain and that this could have repercussion in the acceptability of the treatments. In addition, our participants only tried one of the two modalities (i.e., either DP or OLP) before the qualitative interview. We also are unable to say if the participants recruited in the clinical trial had a specific set of attitudes towards placebo or mind–body treatments that led them to enrol in the first place. In addition, the interviewer was not blind to the group allocation, which might have led to a bias in the non-verbal framing of the questions and to participants' responses. Finally, our study only had a single experience with the placebo treatments. In other studies, patients were offered a course of OLP interventions, which might also influence acceptability factors (Carvalho et al., 2016).

Future studies

The results from this study would usefully be supported by further in-depth qualitative interviews with patients. More specific HCP and patient characteristics might be explored to further understand acceptability of these interventions. For example, demographic factors relating to patients (such as gender, age, education, health insurance status and socio-economic status) may influence acceptability. In addition, HCPs characteristics such as gender, age, communication style, tone of voice, personality factors, accents or perceived attractiveness might influence acceptability. Acceptability might be further complicated by dyadic factors relating to the particular configuration of patients with HCPs (Friesen & Blease, 2018; Howe et al., 2022).

We strongly suggest future studies should focus on providing solid evidence for the effectiveness of OLP before clinical use can be considered. Our study identified the importance to patients of establishing clinical effectiveness of placebo interventions. This also suggested the importance of studying how best to communicate OLP rationale (Heiss et al., 2021; Locher et al., 2017). The preference of DP or OLP seemed to be an individual choice and further studies into what motivates one or the other intervention, for what condition and for whom, are recommended. Trials also need to cover more diversity in the clinical trial samples to better represent the general population. Again, participant diversity could be better included with different pathologies, different cultures, different ages.

Finally, our results suggest that placebo efficacy and acceptability are intertwined. In healthcare, a treatment is usually considered effective if it has a superior effect to a similar inert treatment. However, maybe patients and HCPs do not unanimously define effectiveness in the same way. Our results also showed that effectiveness was sometimes considered a higher priority than autonomy in regard to preference to DP and OLP. This suggests future clinical trials could also compare the effectiveness of OLP to DP through superiority or non-inferiority trials. Going further, if such trials showed positive results, seeing how one positive aspect of placebo treatments was allowing to reduce drug intake, we could also suggest trials comparing the effectiveness and acceptability of OLP and analgesic medications as well as dose-extending OLP in combination with analgesic medications to find the most dose-effective method of administration.

CONCLUSION

Treatment acceptability by patients is a pre-requisite, alongside effectiveness, to harnessing OLP interventions in clinical care. The acceptability of placebo treatments depends on the trust patients have in their HCP, anticipated benefits of treatments and the risks associated with their intake. The preference for DP or an OLP appeared to be a matter of individual choice and context. Finding ways to improve both trust in HCP but also in the OLP rationale when prescribing may be an important next step in studying OLP treatment acceptability. Future research should also focus on what patients want to know about OLP treatments and how to best communicate effectiveness. This goes in tandem with the prerequisite of a patient-centred paradigm whereby communicating benefits and risks as well as preserving trust are fundamental to uphold informed patient decisions.

AUTHOR CONTRIBUTIONS

Leo Druart: Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; validation; visualization; writing – original draft; writing – review and editing. **Oriana Vauthrin:** Conceptualization; data curation; formal analysis; investigation; methodology; validation; visualization; writing – original draft; writing – review and editing. **Nicolas Pinsault:** Conceptualization; formal analysis; funding acquisition; methodology; project administration; resources; supervision; validation; visualization; writing – original draft; writing – review and editing. **Cosima Locher:** Formal analysis; methodology; project administration; supervision; validation; visualization; writing – original draft; writing – review and editing. **Charlotte Blease:** Formal analysis; methodology; project administration; supervision; validation; visualization; writing – original draft; writing – review and editing.

ACKNOWLEDGEMENTS

The authors would like to express their thanks to the APICIL Foundation for funding of the clinical trial as well as the SCREEN platform of the University for their material support. We would also like to express our warmest thanks to SaraEve Graham Longsworth who participated in designing and conducting the clinical trial, which served as a basis for this research.

FUNDING INFORMATION

CL received funding from the Swiss National Science Foundation (SNSF): PZ00P1_201972.

CONFLICT OF INTEREST

The authors declare no conflict of interest. The funding for the clinical trial was provided by APICIL Foundation, which had no part in the methodology or design or data collection or analysis of this study.

DATA AVAILABILITY STATEMENT

The raw data from the interviews that support the findings of this study are available in French from the corresponding author upon reasonable request.

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How to cite this article: Druart, L., Vauthrin, O., Pinsault, N., Locher, C., & Blease, C. (2022). 'It's not my greengrocer, it's someone from the medical profession': A qualitative study regarding acceptability of deceptive and open-label placebo prescribing in France. *British Journal of Health Psychology*, *00*, 1–18. https://doi.org/10.1111/bjhp.12624