Alleviation of Health Complaints Following Regular Consumption of Filtered Tap Water (AcalaQuell®) Is Independent from Placebo Effects:
A Randomized, Double-Blind, Controlled Field Study

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ABSTRACT

Recently, it was shown that regular consumption of a standardized amount of filtered tap water improved the self-reported physical complaints. However, since individuals were fully aware of the type of water they consumed, it was unclear to what extent this effect was ascribable to placebo effects. This paper tests the effectiveness of an in-home water filter system (AcalaQuell®), which was compared with a sham water filter containing no significant filter ingredients. Both filters were concealed, and participants knew that the probability to receive the clinically proven filter was 50%. There were large differences between the two groups ($0.7 < d < 2.0.$). For individual-specific complaints, the reduction was 38% for the filtered water group while the reduction in the placebo group was about 8%. Subjective health complaints are considerably reduced after daily intake of AcalaQuell®-filtered tap water during a three-week administration period. This effect is specific and independent from placebo effects.

KEYWORDS

AcalaQuell, Drinking Water Contamination, Effectiveness, Health Benefit, Health Complaints, In-Home Water Filter, Placebo Effect, Public Health

1. INTRODUCTION

Health is critically dependent on the quality of drinking water (Chowdhury et al., 2019; Clasen et al., 2014; Daughton, 2018; Koopaei and Abdollah, 2017), but many health care professionals tend to somewhat reduce its significance to maintaining physiological functions, e.g., blood pressure, pH, and body temperature (Armstrong and Johnson, 2018; Perrier, 2019). Yet, throughout recorded human history the preventive and curative power of water was well known and part of various therapeutic approaches (Moss, 2010). Even if one disregards or questions the healing properties of water, many entertain a widespread misconception with regard to the quality of drinking water. The rapidly rising number of toxic substances contaminating municipal surface and groundwater impacts all wastewater treatment works (Petrie et al, 2015). Flowing waters used as municipal water supplies also show high concentrations of contaminants which act as vectors for waterborne contaminants or pathogens (Lechner, 2020). However, there is a discrepancy in the understanding of the situation

and its implication for public health. A recent American survey of perceptions about water showed that while 60 percent of the experts recognized that pathogens, fertilizers or pesticides pose a risk to public water systems in the U.S., the majority still rated the water supply as normal or good (Eck et al., 2019). This contradiction could stem from a subjective probability bias or a defense mechanism (Ferrer and Klein, 2015), which is even more accentuated if one takes into account additional factors that may corrupt tap water quality. Apart from microbiological and biochemical concerns, water treatment and transportation are additional potential harmful factors. It has been argued that the intake of 'stressed' water disrupts the water between and within cells in the human body and may prompt pathological macromolecular changes (Davidson et al., 2013). Among such stressors are, e.g., water disinfection (e.g. chlorine or ozone), supplementation (e.g. fluoride), and compression of water through pipe transportation from the supplier to the household. Bottled water, which some regard as a viable alternative, is also contaminated, regardless of whether the bottle is made of plastic or glass. For instance, in a recent study testing 259 bottles from 19 different countries, 93 per cent showed some sign of microplastic contamination (fragments and fibers), which stemmed from both packaging and bottling (Mason et al., 2018). In a large study conducted in Germany, the country with the highest number of bottled mineral water brands, about one third failed to meet the drinking water regulations defined by the EU (Birke et al., 2010). A recent systematic review selecting studies that used procedural blank samples and a validated method for particle composition analysis found that the high-quality studies confirmed strong microplastic contamination of drinking water with the maximum reported contamination of 628 MPs/L for tap water and 4889 MPs/L for bottled water (Danopoulos et al., 2020).

These findings are cause for concern both from the point of view of ecological damage and the burden caused for the health care system. They also suggest that the definition of healthy or 'vital' water warrants reconsideration over and above current regulation policies and recommendations established by national and international health organizations. For example, Pollack (2001) showed that water in the human cell is found in a state of structured aggregation, which he dubbed EZ-water (exclusion zone water). In this state, water homogenously organizes against a hydrophilic surface to form a crystalline structure, 'forcing' other molecules beyond the EZ. Experimental evidence indicates that EZ-water has a negative electric charge which improves its functions for biochemical and structural processes (e.g. by improving the phase angle of tissue, cf. Emilee and Wilhelm-Leen, 2014). Additionally, it also contains higher levels of oxygen, which may help to improve wound healing (Ladizinsky and Roe, 2010), enhance lactate clearance kinetics (Fleming et al., 2017), protect against muscle fatigue (Ivannikov et al., 2017), and boost the immune status and liver function (Grubera et al., 2005). This suggests that there are factors beyond mere contaminants threshold values that influence the quality of the water.

In fact, epidemiological studies support the notion that less-than-optimal household water quality has adverse effects over time, as do natural water sources due to the increase of environmental contamination (Vörösmarty et al., 2010). Health-conscious consumers seek alternative sources, for instance by resorting to point-of-use (POU) water treatment systems which may improve tap water quality, especially with regard to filtering out some of the most commonly known contaminants (Brown et al., 2017). However, there is a general lack of studies investigating such POUs in actual use (i.e. in real life). Recently, the effectiveness of one such POU system, an in-home water filter system, was tested in a pre-clinical sample of adults suffering from various health complaints (Schneider, 2021). According to several chemical analyses this filter system significantly reduces pesticides, bacteria, light-, heavy-, and semi-metals, pharmaceuticals and other major contaminants. The device also aims to revitalize tap water by restoring its original (hexagonal) structure, which is thought to improve the water's bioavailability and biophysiological properties. This claim has not yet been tested empirically, but Schneider (2021) found large health improvement rates after daily consumption of filtered water for three weeks. On average, both physical and mental complaints decreased considerably ($1.0 < d < 1.4$), with individuals suffering from a higher complaint burden at the onset of the study experiencing

stronger symptom relief. However, one methodological caveat concerning the generalizability of this result was the type of control employed. Since the filtered water was tested against a natural control treatment (i.e., unfiltered tap water consumption) placebo effects were not controlled for. Hence, the present study was conducted to test (a) if the effect can be replicated and (b) to what extent it is specific (i.e. ascribable to the consumption of filtered water).

2. MATERIALS AND METHOD

Sample

A total of fifty participants were enrolled in the study (cf. figure 1). Seven individuals met the exclusion criteria, i.e. current intake of pharmacologic agents (n = 4), concurrent medical treatment for the symptoms tested in the study (n = 2), and complaints existing for less than three months (n = 1). Two individuals did not meet the inclusion criteria (i.e., their primary physical complaints did not involve cardiovascular, gastrointestinal, musculoskeletal pain or fatigue symptoms). One participant withdrew from participation after enrollment without specifying further reasons. Based on the effect size found by Schneider (2021), the minimum sample size needed to obtain a power of 1- β = .95 was n = 24 (Faul et al., 2009). Thus, the sample size of n = 40 (22 females and 18 men) was sufficiently large to replicate the effect and to determine whether it was specific. The mean age was 46.6 years (SD = 12.1). The average body weight was 75.1 kilos (SD = 13.9). All participants provided written informed consent and were remunerated with € 20. The study's protocol was run following the Ethical Principles for Medical Research Involving Human Subjects of the World Medical

Figure 1. Flow diagram of randomized and analyzed participants
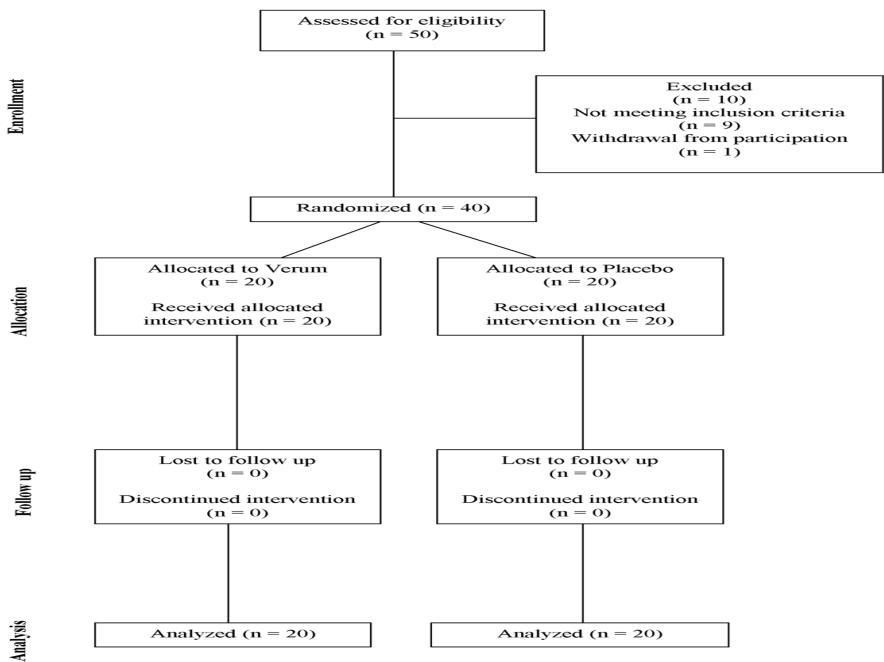
Questionnaires

The Complaints List Revised (CLR)

The CLR is a German self-assessment form to determine subjective impairment caused by physical or general complaints, covering the entire spectrum from absence of complaints to severe impairment (von Zerssen and Petermann, 2011). It consists of 20 items (e.g., fatigue, sleeplessness, nausea, tension) which all load on one general complaint factor. The item format comprises the anchors 'strong' (3), 'moderate' (2), 'barely' (1), and 'not at all' (0). The instrument is used across a wide range of patient groups, i.e. both patients with physical (especially chronic) and mental illnesses or disorders, and in the fields of somatic medicine, medical rehabilitation, clinical psychology, and psychiatry. The internal consistency (Cronbach's alpha) of the CLR is $\alpha = .94$.

Giessen Subjective Complaints List (GSCL)

The GSCL is a questionnaire for assessing the psychosomatic or co-conditioned nature of physical complaints (Brähler et al., 2006). In the clinical realm, it is used to validate medically-caused and subjectively reported symptoms. The 24 items with the anchors 'not' (0), 'barely' (1), 'somewhat' (2), 'considerably' (3), and 'strongly' (4) cover the following complaints: exhaustion (e.g., weariness, excessive need for sleep), gastro-intestinal problems (e.g., stomach aches, nausea), musculoskeletal pain (e.g., pains in joints or limbs, backache), and heart problems (e.g., irregular heart-throbbing, dizziness). The four scales can be aggregated to obtain an overall complaint burden index. Internal consistency of the scales ranges from $\alpha = .82$ (gastro-intestinal complaints) to $\alpha = .94$ (complaint burden).

Individual-specific Symptoms

Since most participants primarily suffered from one predominant medical condition, an individual-specific complaint score was calculated which was derived from one of the GSCL scales. It represented participants' prevalent ailment and thus best reflected any significant changes observed for the treatment. This was also done to minimize the impact of non-relevant complaints that would otherwise lower the complaint burden. In accordance with the first study, this variable was deemed the primary outcome parameter.

Treatment/Intervention

Water Filter

Participants in this condition consumed 35 ml of filtered tap water per kg of body weight per day, following the recommendations of the German Society for Nutrition (DGE) for optimal daily water intake. The amount of water was consumed in small portions throughout the day. Beyond the required amount of water intake, participants were free to consume additional beverages. The filter used (AcalaQuell®) was a jug sized container consisting of a refill unit of 1 liter, a containing unit of 1.3 liters, a pre-filter-unit (microsponge), and a filter cartridge. The filter is non-pressurized and lets the water permeate a 1 μm pore sized microsponge impenetrable to dust, rust, microplastic or other floating particles. Then, it enters the filter cartridge consisting of three different compartments, where (a) an ion exchanger reduces lime, nitrate, and heavy metals, (b) a high-tech activated carbon removes additional potentially harmful substances, like pesticides, or drug residues, and (c) several materials like ceramic-fired tourmaline, calcium, magnesium, magnets, and quartz sand mineralize, structuralize and mildly alkalize the water. The water filter has been tested by several independent microbiological laboratories and has been certified to reduce pesticides. For the purpose of this study the filter was opaque and could not be opened without being physically tampered with. This constituted a safeguard to check participants' adherence/blinding.

(Pseudo) Placebo

Participants in this condition consumed the same amount of 'filtered' tap water. The opaque filter used the same microsponge, but otherwise contained ineffective ingredients, i.e. sand and gravel, which mimicked the water flow of the verum water filter and thus imparted the impression of an active filtering process.

Study Design and Procedure

This field study involved a randomized, placebo-controlled, double-blind design. Participants were contacted individually by the female experimenter who explained the measurement protocol, the questionnaires, and the water filter device. Additionally, participants were handed out the participation information, the operation manual, and the consent form. They were randomly assigned to the treatment conditions using a randomized block design containing five-digit random number sequences that were ranked in ascending succession and assigned to the experimental conditions. After that, the experimenter opened an envelope containing the treatment condition 1 (verum) or 2 (placebo). Participants were told that two types of filters were being tested, one that was proven to eliminate contaminants, and one that was a placebo, and that the probability to receive either was 50 percent. Data collection started on a Monday morning and ended on Sunday night of the third week. At the end of the study, participants were contacted for the second time to return the water filter and questionnaires. Additionally, they were unblinded and remunerated.

DATA ANALYSIS

To assess treatment effects, the effect size d (Cohen, 2008) and confidence intervals (95%) for between-group comparisons were calculated (Borenstein et al., 2009). Dependent variables were difference scores between pre-treatment and post-treatment measures. Calculation of effect sizes was in alignment with meta-analytical practice (Hunter and Schmidt, 2004), the statistics reported by Schneider (2021), and as a consequence of the highly problematic use of Null Hypothesis Significance Testing (Greenland et al., 2016).

3. RESULTS

Symptomatology

At the beginning of the study, twenty-two participants complained primarily about symptoms of fatigue (e.g. weakness, excessive need for sleep), eleven subjects reported stomach/intestinal problems (e.g. bloating, nausea) and seven suffered from of musculoskeletal pain (e.g. joint pain, back pain).

Water Consumption

Compared to the amount of water usually consumed daily (2,487.5 ml), participants drank 2,628.5 ml of water during the study. This difference was statistically insignificant because it fell within positive and negative confidence interval limits ($d = 0.3$; CI: $-0.3 < d < 0.9$). Due to this the amount of water consumed was not included as a covariate in the analyses.

Complaints

The analyses of the individual-specific symptoms as the primary symptom measure showed that the complaints in both groups ranged on average between "somewhat" and "considerable" at the onset of the study. At the end of the study, there was a sizable reduction only in the verum group. It was reduced by about 38 percent after consuming the AcalaQuell® water, while the reduction after consumption of placebo-filtered water was about 8 percent. This difference was large ($d = 1.2$; CI: $0.5 < d < 1.8$;

M_{Verum} 0.78, SD = 0.59 vs. $M_{Placebo}$ = 0.19, SD = 0.42). The effectiveness of the AcalaQuell® filter was 4.9 times larger than the improvement after consumption of placebo filter (see Table 1).

The analysis for the global complaint measure CLR yielded a similar result. Upon using the AcalaQuell® filter, participants' symptoms decreased by about 36 percent, while the reduction after using the placebo filter was 14 percent. This effect was medium to large (d = 0.7; CI: 0.1 < d < 1.4; M_{Verum} 0.34, SD = 0.24 vs. $M_{Placebo}$ = 0.17, SD = 0.22). Likewise, the global burden score of the GBB-24 showed a comparable improvement in the verum group by approx. 38 percent while in the placebo condition it improved by approx. 12 percent. The differential effect, however, was higher (d = 1.3; CI: 0.6 < d < 2, M_{Verum} = 0.52, SD = 0.38 vs. $M_{Placebo}$ = 0.15, SD = 0.12).

With regard to the subscales of the GSCL, there was a larger symptom relief in the verum group than in the placebo group in all four dimensions. For musculoskeletal pain, this effect was very large (d = 2; CI: 1.2 < d < 2.6) and amounted to a relief in the verum group of about 35 percent, while in the placebo group it was about five percent. In absolute terms, pain improved by 0.51 scale points (SD = 0.38) after using the AcalaQuell® filter, and by 0.08 scale points (SD = 0.16) after consuming the placebo filtered water. For gastrointestinal complaints there was a large effect between the study arms (d = 1.2; CI: 0.5 < d < 1.9), such that in the verum group the symptoms were reduced by about 31 percent, and in the placebo condition by about 18 percent (M_{Verum} = 0.62; SD = 0.48 vs. $M_{Placebo}$ = 0.18; SD = 0.21). With regard to exhaustion, a medium to large effect of d = 0.7 (CI: 0.1 < d < 1.3) was found. The percentage changes were approx. 34 percent for verum and seven percent for placebo (M_{Verum} = 0.53; SD = 0.63 vs. $M_{Placebo}$ = 0.16; SD = 0.43). The differential effect for heart complaints was identical to exhaustion (d = 0.7; CI: 0.1 < d < 1.4), the respective changes from pretreatment to posttreatment were 44 percent for verum and 16 percent for placebo (M_{Verum} = 0.34; SD = 0.28 vs. $M_{Placebo}$ = 0.17; SD = 0.19. It should be noted, however, that this symptom complex was not reported as the primary complaint by any participant.

As suspected, the mean scores of both the global scales (CLR, GSCL) and the subscales of the GSCL were not particularly high. For example, at pretreatment the severity for the CLR scale and the total GSCL scale was relatively low (anchor scale "hardly"). As outlined above, this was due to the fact that only few persons suffered from multiple symptoms and therefore the scores in the scales were averaged out. Nonetheless, there were still large effects in symptom reductions after consumption of the AcalaQuell® filter water despite relatively low total symptom burden. This indicated that the water had an effect that was not caused by placebo or expectation effects (see Fig. 1).

Table 1. Means and standard deviations of reported complaints

	Placebo Filter Water		AcalaQuell® Filter Water	
	Pre	**Post**	**Pre**	**Post**
Individual Specific Complaint [a]	2.2 (0.7)	2.1 (1)	2.1 (0.5)	1.3 (0.5)
Giessen Subjective Complaints List [a]	1.6 (0.6)	1.4 (0.6)	1.3 (0.5)	0.8 (0.4)
Exhaustion [a]	2.3 (0.8)	2.2 (1)	1.5 (0.9)	1 (0.7)
Gastro-intestinal Problems [a]	1 (0.6)	0.8 (0.6)	1.6 (0.7)	0.9 (0.4)
Musculoskeletal Pain [a]	1.9 (0.8)	1.8 (0.8)	1.4 (0.5)	0.9 (0.5)
Heart Problems [a]	1 (0.6)	0.8 (0.6)	0.8 (0.5)	0.4 (0.6)
Complaints List Revised [b]	1.4 (0.5)	1.2 (0.6)	1.1 (0.4)	0.7 (0.3)

[†]rounded values; [a] range = 0-4; [b] range = 0-3;

ADDITIONAL ANALYSES

The fact that the range of symptoms varied considerably in the sample suggests that the effectiveness of the AcalaQuell® water filter could have been underestimated. It was conceivable that participants with milder symptoms did not benefit to the same extent. Theoretically and statistically speaking reductions of mild symptoms are less prone to be detected than mitigations of strong ones, which could skew the results. To explore this assumption, the analyses for the differential effects were limited to those individuals who reported an individual complain burden of at least "somewhat" (scale anchor 2), which was the case for n = 21 participants (n_{Verum} = 10; $n_{Placebo}$ = 11). As a result, the mean improvement in the verum group was considerably larger with a reduction from 2.5 (SD = 0.2) to 1.3 (SD = 0.6), corresponding to a burden of "hardly". The results for the placebo group remained unchanged (scale value 2.8 (SD_{pre} = 0.5; SD_{post} = 0.6). The corresponding effect was very large (d = 2.5; CI: 1.7 <d <3.3).

The first study showed that the response rate of individuals profiting from the AcalaQuell® filter was very high (90 percent). In this study, two test persons did not experience any change in their prevalent symptoms, which replicated the aforementioned response rate. The responders' improvement rate ranged between 12 and 87 percent. In contrast, five individuals in the placebo group experienced no changes, and three reported a deterioration of 6-13%. It should not be assumed that the consumption of tap water caused this deterioration however, and it could well be the result of natural fluctuations or the course of symptoms. It is noteworthy, that the three individuals already had a high level of complaints (fatigue) at the start of the study.

The first study revealed that the effectiveness of the AcalaQuell® water filter was higher, the higher the burden of complaints was at the beginning of the study. To explore this relationship, the same analysis was carried out for the present sample. Figure 2 shows the correlation pattern between individual symptom severity at the beginning of the study and symptom improvement at the end. As can be seen, the pattern was opposite for both study arms. While the correlation effect in the verum group was r = 0.67 (d = 1.8), it was r = -0.48 (d = 1.1) in the placebo group. Participants drinking the AcalaQuell® water benefited more the greater their symptoms were initially. In contrast, the symptoms of individuals who drank the placebo filtered water got worse the higher the degree of complaints at the onset of the study. The difference between the correlations was large (Cohen's q = 1.3).

Figure 2. Mean symptoms improvement (pretreatment minus posttreatment); scale range: CLR = 0-3; GSCL = 0-4
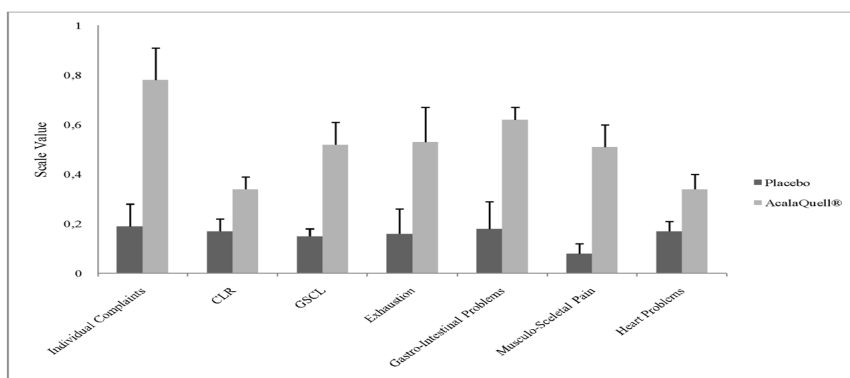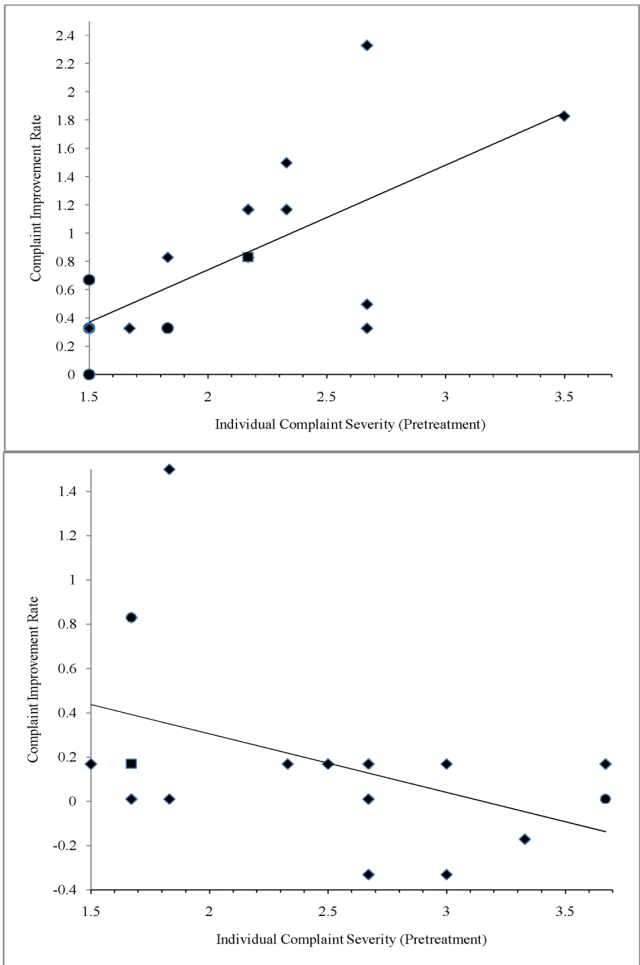
Figure 3. Correlation between individual complaint burden and symptom relief; upper half: AcalaQuell®, lower half: Placebo; squared marks: three overlapping data points; circles: two overlapping data points

4. DISCUSSION

The aim of this study was to test whether the effectiveness of the AcalaQuell® water filter system was due to mediating placebo effects or the direct result of consumption of filtered water. The results indicated both overall and individual-specific complaint reductions that were highly specific. The pattern of results in this study matched those of the first, both with regard to the effect size ($d = 1.2$ vs. $d = 1.4$) and the percentage decrease (30 percent vs. 26 percent). The size of the effect is demonstrated by the fact that 88.5 percent of the participants in the verum group had an improvement rate that was above the mean of the placebo group. As expected, there were distinct interindividual differences in response rate, with some individuals showing smaller improvements while others experienced greater symptom relief. As in the first study, there was a strong relationship between effectiveness of the AcalaQuell® filter system and symptom severity such that individuals suffering from stronger symptomatology benefitted to a stronger degree. Overall, the effectiveness of the AcalaQuell® water filter was replicated, and the effect was not mediated by placebo effects, which is corroborated by the fact that the specific effect exceeded the placebo effect by 275 percent.

The observation that the placebo filter only produced a small effect suggested that the microsponge exerted no notable effect on complaint symptomatology, as it was also part of the placebo filter. Thus, the improvement in the verum group must have been caused by the components of the filter, which, besides purifying, mineralizing, and alkalizing tap water, claims to "structure" it. The nature of this study did not allow investigation of this assertion. There are, however, orthodox explanations for the complaint-reducing effect. For instance, improved water quality enhances its cleansing properties by assisting the kidneys in removing waste products from the blood and eliminating toxic substances in the urine. Such effects have been shown to alleviate symptoms of fatigue (Pross et al., 2014). Likewise, gastro-intestinal disturbances may be improved by altering drinking water pH, which may affect the gut microbiota and glucose regulation (Sofi et al., 2014). However, as mentioned in the introduction there are a number of studies supporting the notion that there may be medical effects of structured water that, in principle, might have added to the beneficial effect of this water filter system.

The results of this work are potentially beneficial to both private health and the public health care system. Epidemiological data suggest that the continuous increase of contaminants in drinking water become increasingly resistant to metabolization or excretion. Their role in causing oxidative stress, which is symptomatic for numerous detrimental health effects, involving cancer, cardiovascular disease, diabetes, atherosclerosis, and neurological disorders, is well documented (Chowdhury et al., 2019; Jomova and Valko, 2011). Although there are many point-of-use (POU) water treatment systems, ranging e.g. from distillation, reverse osmosis, activated carbon filters, ultraviolet treatment, or cation exchange resin beads, the empirical evidence for their usefulness is scarce. The result of this study is in alignment with evidence suggesting that the use of an effective water filter is associated with reductions in health problems even when the quality of the sources is accounted for (Bain et al., 2012; Wolf et al., 2014). Thus, the regular use of filtered water from the AcalaQuell® system may promote health at least in subclinical populations and reduce long-term public health care costs caused by consumption of contaminated water.

There are several questions this work could not address. For instance, subjective health complaints and medical symptoms may or may not covary. Phenomenological (i.e. experienced) complaints may not have an actual clinical causation and therefore cannot be quantified organically or functionally (i.e. objectively). Rather, they may manifest as physical symptoms that are caused by psychological factors (e.g. life stress). Conversely, patients with a diagnosed illness may be symptom-free and thus do not experience complaints (e.g., hypertension). On average, subjective complaints and objective health issues only correlate moderately, and therefore the results of this study await confirmation beyond merely subjective health issues. Nonetheless, subjective complaints should not be dismissed as insignificant, as they exist even if they have no medical foundation. The fact that this study demonstrated a highly specific effect on subjective health complaints attests to that.

One aim of this study was to investigate a POU filter system in actual use and in a natural environment. As such, the results are externally valid. There are many factors, however, that could not be accounted for, for instance, adherence to the study protocol, water installations on site, or the supplier's water quality. Furthermore, only a relatively limited period of time was investigated and participants were not followed-up upon. Future studies should account for these factors and employ research designs that allow drawing conclusions for different types of ailments, outcome parameters (e.g. biomarkers, medical diagnoses), and samples (clinical vs. non-clinical).

With regard to the therapeutic use of the device future studies should shed more light on the filter's capacity to expedite or complement other treatments, e.g. during convalescence, recuperation and therapeutic treatment. Although the filter is not designed as a medical tool, its effectiveness could be utilized and extended to the clinical realm. Such studies should also employ techniques in more controlled environments that allow investigation of biomedical factors which act as mediating factors to restore health. In doing so, the questions if and how the filter actually structures water should be elucidated since this might substantially contribute to our understanding of the healing properties of water.

5. CONCLUSION

The AcalaQuell® water filter system substantially reduces subjective health complaints. The effect is large and shows already after three weeks of regular daily water intake. The consumption of filtered water may reduce individual health issues, potentially preventing ensuing organic and/or medical health problems and may thus be an effective tool to reduce public health costs associated with contaminated drinking water.

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