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Mobile phone base stations and well-being — A meta-analysis

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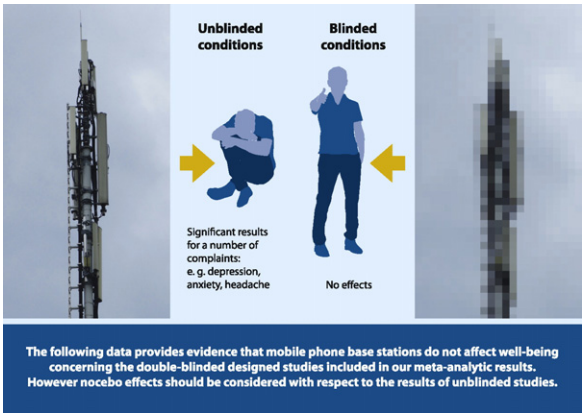
HIGHLIGHTS

- Our meta-analytic results provide evidence that mobile phone base stations do not affect human well-being.
- When concerning unblinded studies nocebo effects should be considered.

GRAPHICAL ABSTRACT



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ABSTRACT

It is unclear whether electromagnetic fields emitted by mobile phone base stations affect well-being in adults. The existing studies on this topic are highly inconsistent. In the current paper we attempt to clarify this question by carrying out a meta-analysis which is based on the results of 17 studies. Double-blind studies found no effects on human well-being. By contrast, field or unblinded studies clearly showed that there were indeed effects. This provides evidence that at least some effects are based on a nocebo effect. Whether there is an influence of electromagnetic fields emitted by mobile phone base stations thus depends on a person's knowledge about the presence of the presumed cause. Taken together, the results of the meta-analysis show that the effects of mobile phone base stations seem to be rather unlikely. However, nocebo effects occur.

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1. Introduction

In view of the increasing use of mobile phones, potential impacts of electromagnetic fields emitted by base stations are of great public interest (Augner et al., 2012). The single base stations support a cellular

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system, keep track of the mobile phones within a cell, provide the connection and handle the carry-over to the next one, if a user moves from one cell to another (Kundi and Hutter, 2009). Due to the increasing numbers of providers, the number of base stations keeps growing (Khurana et al., 2010; Kundi and Hutter, 2009).

Effects on a wide range of health parameters such as cognitive functions, well-being, sleep and even cancer have been discussed over the last decade (Kundi and Hutter, 2009; Röösli et al., 2010). However, the findings have been ambiguous and inconsistent. There are different endpoints, study designs and target populations that can be studied which have different intrinsic difficulties and problems. Concerning endpoints, (chronic) diseases, physiological indicators, well-being, and performance indicators can be differentiated. Acute effects of base station signals can be studied experimentally in the lab or in the field, and also observational studies can be carried out applying different methodologies such as exposure estimation, spot measurements, or personal dosimetry. The study of chronic effects affords an epidemiological design with cross-sectional, case–control, or cohort studies as the most frequent types. There are a number of crucial problems for investigating the effects of base station signals (Hutter et al., 2006; Neubauer et al., 2007). The first problem concerns the proper definition of the independent variable: exposure to base station signals is defined by three aspects — (average) intensity, duration, and pattern (time course) of exposure. There is an infinite number of possibilities to map these three aspects into a (feasibly small) set of exposure indicators. While field studies contain the risk of missing crucially important exposure characteristics, experimental studies face the problem of deciding about the appropriate manipulation of these characteristics, since experimental conditions must be restricted to but a few. Another problem concerns appropriate outcome assessment. In experimental trials including people suffering from "idiopathic environmental intolerance with attribution to electromagnetic fields (IEI-EMF)", the lab conditions might cause too much arousal to observe any additional effect of base station signals on subjective well-being, physiological or performance indicators. The limitations of sensitivity of the outcome assessment are not restricted to experimental investigations, but also extend to field studies. In general, test procedures designed for discriminating in the pathological range are not suitable for the study of the general population living near base stations. A further problem is the selection of the appropriate study population. It has to be borne in mind that although base stations are ubiquitous, actual exposure intensity is very low and rarely exceeds a few tenths of a microwatt per meter squared. Therefore, a random selection from the general population carries the risk of finding too few persons or virtually no-one who can be considered exposed. Another issue, especially if subjective symptoms are targeted, is concerns about adverse effects by study participants, as these could distort and bias outcome assessment. Appropriate control for such concerns is therefore an important design aspect. While these and other difficulties must not be neglected, there is no reason to consider studies of base stations unfeasible.

At first sight, the results of the various studies about the effects of EMF may seem inconsistent, providing strikingly significant results as well completely inconspicuous ones. However, a more detailed inspection tells that this variation closely follows the variation in approach and design of the different studies, and in the different criteria on which the evaluation was based.

Field studies tend to report significant effects regarding the distance to EMF in real life regarding some aspects of well-being, but not for all of them. On the other hand, actual exposure measurements are less successful in predicting symptoms: In a cross-sectional study, Hutter et al. (2006) found increased risks for headache, vegetative symptoms, and concentrations difficulties, but no significant effects on sleep quality were detected, at least if concerns about negative health effects of the base station were controlled for. In contrast, Blettner et al. (2009) found a significant relationship between distance to the nearest base station (less than or more than 500 m) and subjective symptoms *even after* correcting for concerns about effects of base stations. However, in a subgroup of this sample with actual measurements, Berg-Beckhoff et al. (2009) found no difference in symptoms when comparing extreme groups regarding exposure, but actual exposure was very low even for the high-exposure group. Abdel-Rassoul et al. (2007) diagnosed inhabitants living near mobile phone base stations to be at risk of developing neuropsychiatric problems and changes in performance during neurobehavioral tests. Studies from Germany applying personal dosimetry revealed various results as well: while Heinrich et al. (2007) found some symptoms significantly related to exposure and Thomas et al. (2010) observed a significant increase in conduct problems in children and adolescents, no significant effects were reported by Thomas et al. (2008) concerning acute and Heinrich et al. (2007) concerning chronic symptoms in adults. Bortkiewicz et al. (2012) found an increased prevalence of headaches at a distance of 101–150 m from the base station where the highest levels of exposure can be expected (Viel et al., 2010), but no association with actual measurements which were, again, flawed by participant's low exposure. In a series of investigations by the Qualifex team, Basel, Switzerland, combining a cross-sectional and follow-up design, Mohler et al. (2010, 2012), Röösli et al. (2010); Röösli and Hug (2011) and Frei et al. (2012) found no indications of strong relationships between exposure to stationary sources of EMF and various health-relevant endpoints. However, exposure levels in the highest exposure groups were still extremely low because of the random sampling of participants (only 10% were exposed above a level of 0.05 mW/m^2).

In stark contrast, in blinded experiments – where people could not know about the exposure condition they are in – well-being measures seem rather unaffected by EMF exposure: Regel et al. (2006) could not confirm a short-term effect of base station-like exposure on well-being that was observed in an earlier study by Zwamborn et al. (2003) (whereby the findings of the Zwamborn study are no longer significant when corrected for multiple testing). The study carried out by Riddervold et al. (2008) observed an increase in the 'headache rating' when data from adolescents and adults were combined. In a laboratory experiment in women with and without self-reported symptoms when using a mobile phone, Furubayashi et al. (2009) found no evidence of any difference in symptoms during exposure to EMF from base station signals between these groups. In a field-intervention study, Danker-Hopfe et al. (2010) did not detect any short-term effects of EMF on objective and subjective sleep quality. Wallace et al. (2010, 2012) investigated a TETRA (terrestrial trunked radio) base station in a semianechoic chamber and subjects with and without self-reported hypersensitivity to EMF, but no significant difference in physiological responses was reported between both groups and between sham and actual exposure. Eltiti et al. (2007, 2009) found that short-term exposure to an experimental base station signal did not affect physiological functions in sensitive or control individuals. However, in particular sensitive individuals had reduced well-being under an open-provocation condition in Eltiti et al. (2007) and Wallace et al. (2010), which means under a condition where they explicitly knew whether they were exposed or not.

Because of the inconsistency regarding the study designs, actually leading to inconsistency of the results, the following systematic meta-analysis will have to split between different types of studies: blinded experimental studies, unblinded (open provocation) experiments, and field studies.

2. Materials and methods

We used PubMed for our literature search by focusing on articles published in English until July 2014. The search procedure consists of the following steps:

First we used the following phrases: "mobile phone base station", "cellular phone base station", "cell tower". In the second step we excluded all studies on animals and children. Third, we focused on papers dealing with measures or symptoms (e.g. headaches, dizziness, fatigue)

related to well-being in the meaning of any kind of undesirable psychological state. Fourth we excluded papers containing no original data. In addition, we screened the reference lists of all papers found.

After screening, the following seventeen studies were included in the quantitative meta-analysis: Abdel-Rassoul et al. (2007), Augner et al. (2009), Augner et al. (2009), Berg-Beckhoff et al. (2009), Blettner et al. (2009), Bortkiewicz et al. (2012), Danker-Hopfe et al. (2010), Eltiti et al. (2007), Furubayashi et al. (2009), Hutter et al. (2006), Regel et al. (2006), Riddervold et al. (2008), Thomas et al. (2008), Wallace et al. (2010), Wallace et al. (2012), Gómez-Perretta et al. (2013) and Shahbazi-Gahrouei et al. (2014). Table 1 shows the main characteristics of these studies.

Unfortunately, the designs of the different studies and the benchmarks against which the effects are evaluated are heterogeneous across these studies, so that comparability is quite limited. In order to nevertheless obtain a stable conclusion, we applied two different approaches: first, before we applied standard meta-analytic procedures which aim at pooling the statistical effect size in different samples into one, we started by evaluating the p-values only, representing the largest commensurable piece of information. Technically, this means combining independent p-values across different studies by means of Fisher's well-known formula. To guarantee the independence of the p-values, only one value per independent data set and symptom (endpoint) was taken.[2]

As the second approach, standard meta-analytical techniques were applied to aggregate statistical information for a number of particular symptoms. The procedure of summing up effect sizes (weighted by sample size) followed the methodology described in Borenstein et al. (2011): we converted the different effect sizes to correlation coefficients r (following the recommendation by McGrath and Meyer (2006), for the case of heterogeneous designs across studies) and tested for heterogeneity and significance of the aggregated information by means of the usual formulas (random effects model) using the R-package meta (Viechtbauer, 2010). To be included in such an evaluation for a single symptom, the results of this variable had to be supported by sufficient information to convert the study's effect size into a correlation equivalent.

The meta-analysis was carried out for three different types of study designs: I) experimentally manipulated and blinded conditions, II) experimentally manipulated unblinded conditions (with open exposure) and III) field studies with real mobile phone base stations.

Table 1
Characteristics of the studies included in the meta-analysis.

Reference	Study design	N	Male/female
Abdel-Rassoul et al. (2007)	c	85	Male 48 Female 37
Augner and Hacker (2009)	c	57	Male 22 Female 35
Augner et al. (2009)	a	57	Male 22 Female 35
Berg-Beckhoff et al. (2009)	c	3526	Male 1573 Female 1953
Blettner et al. (2009)	c	30047	Male 14399 Female 15648
Bortkiewicz et al. (2012)	c	500	Male 181 Female 319
Danker-Hopfe et al. (2010)	a	397	Male 195 Female202
Eltiti et al. (2007)	a,b	176	Male 100 Female 76
Furubayashi et al. (2009)	a	54	Male 0 Female 54
Hutter et al. (2006)	c	365	Male 150 Female 215
Regel et al. (2006)	a	117	Male 55 Female 62
Riddervold et al. (2008)	a	80	Male 41 Female 39
Thomas et al. (2008)	c	322	Male 155 Female 173
Wallace et al. (2010)	a,b	183	Male 71 Female 112
Wallace et al. (2012)	a	180	Male 84 Female 96
Gómez-Perretta et al. (2013)	c	88	Male 45 Female 33
Shahbazi-Gahrouei et al. (2014)	c	250	Male 117 Female 133

Note. Sample: a = double blind, b = experiment unblinded, c = field study.

3. Results

3.1. Type I: blinded experiments

None of the fully blinded studies of Type I contributed significant p-values to the globally (across different symptoms) combined p-value of 0.545. Table 2 lists the studies and the corresponding assessment instruments. The IEI-EMF property (meaning the Idiopathic environmental intolerance attributed to electromagnetic fields (IEI-EMF), that is characterized by various, non-specific physical symptoms that occur, when an EMF source is present or perceived by an individual (Baliatsas et al., 2012)) did not influence these results in any noticeable way, so the aggregated evaluation across both groups may be considered sufficient.

Additionally, no significant results were obtained for single symptoms where the information in the articles allowed for the aggregation of p-values (Table 3). Except for two slightly significant p-values in Eltiti et al. (2007), no significant p-values occur at all in the studies, and also these two would not be significant applying any consideration of the multiple testing problem. Therefore, the set of available double-blind studies provides no indication for any effect of mobile phone radiation on human well-being.

3.2. Type II: unblinded experiments

Only two studies are available representing Type II (experimental but unblinded setting), Eltiti et al. (2007) and Wallace et al. (2010) enter with the same indicators as before, but with completely opposite results now ($p < 0.0001$ or $p = 0.02$, resp., together $p < 0.0001$). Both compare open vs. hidden exposure and only obtain a significant result for open exposure. Unlike fatigue ($p = 0.27$), all of the symptoms discomfort, anxiety and tension reached highly significant p-values ($p < 0.0001$) individually (see Table 3). It has to be noted that both studies involve persons with or without claimed IEI-EMF which generates two subsamples with possibly different effects. In particular, effects of the open provocation are – not surprisingly – larger for persons with IEI-EMF than without. Since the current meta-analysis aims at an objective cumulative evaluation of all studies available, the authors abstained from any additional consideration for selection or weighting of participants but present the data for the two groups plainly aggregated. But we may add the information that even the group without IEI-EMF

[2] As a further complication, many of the studies do not indicate primary and secondary end points, but merely report several p-values. Since an evaluation of that kind needs independent p-values, they had to be transformed into only one per independent data set. To avoid both an arbitrary selection as well as type I error inflation for k different tests in an article, a decision was taken to evaluate how likely it would be under null distribution that the minimum of the p-values would be as small as the one observed. Thereby, as an approximation, the independence of the p-values was assumed. The probability for pmin being the smallest p-value out of k results in $1 - (1 - \text{pmin})^k$. However, the results were cross-checked by inverting the well-known Bonferroni correction (not requiring independent p-values), which led to substantially the same results.
If the same criterion was tested for the same groups but at two time points, the average p-value was taken. If p-values were presented for two groups separately, they were combined using the Fisher formula. (This procedure was chosen to aggregate the information in Regel et al., 2006; as before, the results are too clear-cut to be sensitive to methodological details here).

Table 2
Assessment instruments of the studies included in the meta-analysis.

Reference	Assessment
Type I: blinded experiments	
Augner et al. (2009)	Symptom Check List SCL-90 (Franke and Derogatis, 2002) State-Trait Anxiety Inventory STAI(Laux and Spielberger, 1981) Multidimensional Well-Being Questionnaire MDBF (Steyer et al., 1994)
Danker-Hopfe et al. (2010)	A score for subjective sleep quality
Eltiti et al. (2007)	Symptom score from an Electromagnetic Hypersensitivity Questionnaire
Furubayashi et al. (2009)	Profile of Mood States, POMS (McNair et al., 1992)
Regel et al. (2006)	Quality-of-Life Questionnaire (Zwamborn et al., 2003)
Riddervold et al. (2008)	Several well-being symptoms rated by a visual analog scale
Wallace et al. (2010)	Symptom score from an Electromagnetic Hypersensitivity Questionnaire
Wallace et al. (2012)	Blood volume pulse, heart rate, and skin conductance
Type II: unblinded experiments	
Eltiti et al. (2007)	Symptom score from an Electromagnetic Hypersensitivity Questionnaire
Wallace et al. (2010)	Symptom score from an Electromagnetic Hypersensitivity Questionnaire
Type III: field studies	
Abdel-Rassoul et al. (2007)	A questionnaire by Abdel Gawad (1972) on neurological complaints
Augner & Hacker (2009)	Symptom Check List SCL-90 (Franke and Derogatis, 2002) State-Trait Anxiety Inventory STAI (Laux and Spielberger, 1981) Multidimensional Well-Being Questionnaire MDBF (Steyer et al., 1997)
Berg-Beckhoff et al. (2009)	Several well-being scales: Pittsburgh Sleep Quality Index PSQI (Buysse et al., 1989) Headache Impact Test HIT-6 (Kosinski et al., 2003) von Zerssen List of Complaints (von Zerssen, 1976) Profile of Mental and Physical Health SF-36 (Bullinger and Kichberger, 1998) Trier Inventory of Chronic Stress TICS (Schulz et al., 2004)
Blettner et al. (2009)	Frick symptom score (Frick et al., 2002)
Bortkiewicz et al. (2012)	Specific questionnaire
Gómez-Perretta et al. (2013)	A clinical symptoms checklist
Hutter et al. (2006)	von Zerssen List of Complaints (von Zerssen, 1976)
Shahbazi-Gahrouei et al. (2014)	A standardized questionnaire about various symptoms
Thomas et al. (2008)	Freiburger Beschwerdeliste (Fahrenberg, 1975; Hiller, 1997) von Zerssen List of Complaints (von Zerssen, 1976)

reaches a significant effect ($p = 0.029$) between sham and real exposure for the same symptoms as the aggregated sample: discomfort, anxiety, and tension.

3.3. Type III: field studies

Field studies about the relationships between health or well-being and the presence of a mobile phone base station or other kind of open exposure created a more diverse picture. (Again, the studies and the assessment instruments which were applied are found in Table 2.) Though some of them did not use the objective or subjective distance but the actual exposure (which is not directly observable by the participants, and unlikely to be measured), the presence of the source of EMF still cannot be assumed to be fully blinded. All authors except for Hutter et al. (2006) ($p = 0238$), Berg-Beckhoff et al. (2009) ($p = 0.946$, since none of the 6 criteria even fulfilled $p < 0.40$), and Thomas et al. (2008) ($p = 0.533$) obtained a significant result, which produces an aggregated p-value far below 0.0001; the Blettner et al. (2009) and Gómez-Perretta et al. (2013) studies reach this level individually, Shahbazi-Gahrouei et al. (2014) not quite ($p = 0.0014$), while the Augner and Hacker (2009) article yields 0.044. Bortkiewicz et al. (2012) show a few single significant measures (headache, $p = 0.013$, impaired memory, $p = 0.004$, dermal changes, $p = 0.006$), but out of no less than 15 endpoints and, in part, after post-hoc selection of the groups to be compared, whereby the corresponding correction produces a non-significant value. However, also at this place the necessarily very conservative correction does not influence the final result.

Regarding single symptoms, aggregated p-values could be obtained for several complaints in unblinded designs (Table 3): anxiety, fatigue, headache, depression, lack of concentration, dizziness (or vertigo), and irritability.

In contrast to the situation with blinding of conditions, *all* symptoms produced markedly significant results, either via Fisher's combination of p-values or by aggregating effect sizes, whereby either the aggregated effect size is significant or the test for homogeneity of effect sizes (all measures except for anxiety and tension), implying that at least some of the studies have effects which are different from zero. The numerical outcomes of the (in most cases infeasible) aggregation of effect sizes would suggest effects comparable to correlations between 0.1 and 0.4.

Taking all these results together, there seem to be no effects in the blinded experiments, but highly significant outcomes in the unblinded Type III field studies, and for most of the measures of Type II (unblinded experiments).

4. Discussion

When considering double-blind experimental studies, we found no effects of electromagnetic fields emitted by simulated mobile phone base station signals on human well-being within the 30 to 50 min of exposure used in these experiments. By contrast, unblinded experimental conditions in these provocation experiments clearly showed effects. This discrepancy provides strong evidence of results depending on the study design. One possible explanation is that the detrimental effects of mobile phone radiation on well-being depend on knowledge about its presence. This suggests that the mechanism is of a nocebo type.

Similar effects have been observed in studies on mobile phones: Kwon et al. (2008) showed that people were unable to perceive electromagnetic fields above chance levels under blinded conditions. Kwon et al. (2012) and Nam et al. (2009) demonstrated in double-blinded provocation studies, that persons with presumed IEI-EMF were not able to detect electromagnetic fields better than people without IEI-EMF. Furthermore no physiological changes or subjective symptoms were observed in both groups (IEI-EMF and non-IEI-EMF).

However, though a noticeable physical effect is very unlikely, the nocebo effect in our present analysis is so striking and so consistent across the studies that it should be taken into account, for example by means of re-considering communication strategies concerning mobile phone technology in general. Some people obviously distrust mobile phone technologies to an extent that leads to measurable detrimental effects on their self-rated well-being.

Our meta-analytic approach is limited by several points. Since the level of heterogeneity across the studies did not allow for much information on single symptoms under comparable conditions, the evidence for specific effects is limited. Especially for objective physical effects, this meta-analysis cannot replace targeted analysis, should there be a specific hypothesis about particular symptoms.

Regarding the significant field studies, distance to a mobile phone base station could be confounded by sociodemographic variables such as income, or by characteristics of the specific surroundings of the base stations in question in a single study. As a less controllable confounding variable, the questionnaires in the unblinded studies could have drawn the attention of the participants to the presence of mobile phone base station radiation and therefore created an effect which might have been less drastic in everyday life.

Table 3
Overview over single symptoms which allow for the aggregation of p-values. Correlation equivalent and p-value per study; Fisher's p, aggregated correlation equivalent with p-value and heterogeneity p-value per area and type of design.

		Augner, Florian et al.	Eltiti	Augner & Hacker	Hutter	Wallace	Riddervold	Bortkiewicz	Furubayashi	Thomas	Abdel-Rassoul	Gómez-Perretta	Shahbazi-Gahrouei	Fisher's p	Number of Studies	Aggregated r	Aggregated p-value (correlation)	p-Value for heterogeneity
Field	n			57	336			500		152	165	88	150					
Depression	p			0,23				0,08			0,04	0,0002	0,75	0,0004	5			
	r			0,20				0,13			0,27	‡	0,05			0,15	<0,0001	0,31
Fatigue	p				0,45			0,45		0,98		<0,0001	0,00	<0,0001	5			
	r				0,04			0,05		−0,10		0,09	0,24			0,15	0,13	<0,0001
Headache	p				0,02			‡		0,40	0,04	<0,0001	0,00	<0,0001	5			
	r				0,14			‡		0,05	0,27	0,10	0,28			0,10	0,23	0,0002
Anxiety	p			0,03								??		0,03	1			
	r			0,36								0,09				0,36	0,03	–
Concentration	p				0,04					0,40	0,32	<0,0001		<0,0001	4			
	r				0,12					−0,02	0,16	0,68				0,30	0,16	<0,0001
Dizziness	p				0,31						0,01	<0,0001	0,00	<0,0001	4			
	r				0,19						0,38	0,69	0,00			0,39	0,07	<0,0001
Irritability	p										0,38	<0,0001	0,22	<0,0001	3			
	r										0,11	0,68	0,21			0,30	0,17	<0,0001
Open Provocation	n		176			183												
Discomfort	p		<0,0001			<0,0001								<0,0001	2			
	r		0,30			0,30										0,30	<0,0001	0,97
Fatigue	p		0,48			0,16								0,27	2			
	r		0004			0,08										0,04	0,42	0,47
Anxiety	p		0,0002			<0,0001								<0,0001	2			
	r		0,30			0,31										0,31	<0,0001	0,92
Tension	p		<0,0001			<0,0001								<0,0001	2			
	r		0,29			0,39										0,34	<0,0001	0,28
Blind	n	57	176			180			108									
Depression	p	0,79							0,78					0,91	2			
	r	0,07							0,03							0,04	0,59	0,80
Discomfort	p		0,54			0,33								0,48	2			
	r		−0,01			0,03										0,01	0,87	0,69
Fatigue	P	0,34	1,00			0,51			0,41					0,73	4			
	r	0,11	−0,20			−0,001			−0,04							−0,05	0,39	0,13
Anxiety	p		0,05			0,44			0,60					0,19	3			
	r		0,11			0,01			0,03							0,05	0,25	0,61
Concentration	p						0,58		0,77					0,80	2			
	r						–		0,02							0,02	0,77	–
Tension	p		0,04			0,44			0,60					0,17	3			
	r		0,13			0,01			0,03							0,06	0,19	0,49

‡ indicates that the published information was not sufficient to compute a value for this cell.

Another problem is that there are still too few studies on base stations overall. Following Kundi and Hutter (2009), the major part of investigations on the effects of electromagnetic field exposure on health focuses on cellular phones. This is regrettable, because the exposure created by base stations is clearly different to that caused by mobile phones. Exposure to mobile phones occurs intermittently, whereas that caused by base stations is continuous. Mobile phones predominantly affect the area of the head, while base stations affect the whole body.

A further problem is the retrospective recording of cumulative exposure by base stations and similar exposure sources. This methodological difficulty is ignored by almost all of the studies. Another limitation for the assessment of long-term effects is the short period of time this technology has been in use.

A fundamental problem is that long-term effects can only be investigated under unblinded conditions but not in double-blind experiments. Therefore, the discrepancy between significant field studies and non-significant experiments is not necessarily due to nocebo effects under unblinded conditions. It could also result from the fundamental incapability of experiments to deal with the long-term effects of real-life exposure to EMF from base stations.

In summary, we can conclude that at least short-term negative effects of mobile phone base stations on adult humans seem to be a nocebo phenomenon. Possible long-term effects should be the focus of future research.

5. Conclusions

In conclusion, our data provide evidence that mobile phone base stations do not affect human well-being in the double-blinded designed studies included in our meta-analytic results. However, nocebo effects should be considered with respect to the results of unblinded studies.

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