

Behavioural research¹ and the WMO

Behavioural research comes within the scope of the WMO if the following conditions are met (section 1, subsection 1, paragraph b, of the WMO):

- the research is of a medical nature;
- the subjects receive a particular treatment or are asked to behave in a particular way.

Medical research

The extent to which psychological research involving human subjects may be regarded as ‘medical’ depends in principle on how one defines the word ‘medical’. In the absence of a precise legal definition of this term, it may generally be assumed that behavioural research has a medical element if it is likely to yield findings beneficial to medical science or the practice of medicine (see section 3, paragraph a, of the WMO).

Subjects receive a particular treatment or are asked to behave in a particular way

At various points in the parliamentary consideration of the bill enacting the WMO, it was expressly stated that behavioural, paramedical and nursing research would come within the scope of the WMO² in cases where the subjects received a particular treatment or were asked to behave in a particular way. Hence, a study that involved the completion of a questionnaire or questionnaires would not in principle come within the scope of the Act, unless either the frequency with which a subject was asked to complete a questionnaire were sufficient to bring about a temporary change in the subject’s lifestyle or the (psychologically probing) nature of the questions were such that the subject could be regarded as having received a particular treatment or having been asked to behave in a particular way. This further limits the applicability of the WMO to behavioural research, since (empirical) behavioural research often makes use of pre-existing data files, one-off questionnaires or interviews, without compromising the physical or psychological integrity of the subject in any way. Given the medical impact criterion set out above, most of the behavioural research that comes within the scope of the WMO will be psychological research³. Some examples of psychological research falling within the scope of the Act are given below.

Examples of psychological research in which subjects receive a particular treatment

- Psycho-physiological stress experiments, in which subjects are subjected to a frustrating procedure. For example the subject is asked to perform a complex mathematical calculation and (routinely) told that his/her performance is substandard.⁴
- Social psychology experiments, which seek to determine the extent to which the pressure to behave in a conformist manner leads to disregard for important standards and values
Example: the classic study conducted by Milgram, which investigated subjects’ willingness to

¹ Behavioural research includes the description and explanation of observations, feelings, thoughts and actions.

² See Proceedings of the Lower House, 1991-1992, 22 588, no. 3, p 7, Proceedings of the Lower House, 1995-1996, 22 588, no. 7, p 18, Proceedings of the Lower House, 1995-1996, 22 588, no. 11, p 10.

³ The possibility cannot be excluded, however, that studies within other social science disciplines may occasionally require review in accordance with the WMO.

⁴ Stronks DL, Tulen JH, Verheij R, Boomsma F, Fekkes D, Pepplinkhuizen L, et al. Serotonergic, catecholaminergic and cardiovascular reactions to mental stress in female migraine patients. A controlled study. *Headache* 1998;38(4):270-280.

give strangers electric shocks when instructed to do so by an 'authority figure' (actually a research assistant).⁵

- The injection of subjects with stress-hormones for the purpose of enabling experimental psychologists to study emotions. For example the classic experiment performed by Schachter and Singer, who injected some of their subjects with catecholamines to study (amongst other things) the influence of physiological processes on emotions.⁶
- Experiments designed to enable experimental psychologists to study memory functions. For example research into the possibility of inducing false memories (memories of things that have not happened) in children.⁷
- Clinical psychology, and health psychology and medical psychology research into the way people deal with serious events. For example interviews with pregnant women who have been informed that their foetuses have life-threatening conditions, designed to gather information about their thought processes and decision-making concerning the remaining course of the pregnancy.⁸

Examples of psychological research in which subjects are asked to behave in a particular way

- Clinical psychology research which involves asking subjects to report on their own condition very frequently and/or over an extended period. For example a study in which migraine sufferers are asked to make entries in an electronic stress diary four times a day over a period of months in order to provide information about the temporal relationship between stress-events and migraine attacks.⁹
- Medical psychology research involving the use of ambulant measurement techniques. For example a study in which migraine sufferers are asked to wear movement and heart-rate monitors with electrodes attached to their bodies for several consecutive days, both before and after attacks, with a view to determining the effect that migraine attacks have on mobility and heart rate patterns in day-to-day life.¹⁰
- Psychometric research in which subjects are required to complete questionnaires for hours on end. For example research into the intelligence and personality of migraine patients, in which patients are asked to complete numerous personality questionnaires and to perform neuropsychological and intelligence tests.¹¹
- Research in the field of clinical psychology designed to investigate the efficacy of behavioural therapy strategies. For example young people suffering from chronic pain or headache are

⁵ Milgram S. Obedience to authority: an experimental view. New York: Harper & Row;1974.

⁶ Schachter SS, J. E. Cognitive, social and physiological determinants of emotional state. Psychol Rev 1962;69:379-399.

⁷ Herrmann D, Yoder C. The potential effects of the implanted memory paradigm on child subjects. Appl Cognitive Psychol 1998;12(3):198-206.

⁸ Hunfeld JAM, Wladimiroff JW, Verhage F, Passchier J. Previous stress and acute psychological defence as predictors of perinatal grief – an exploratory study. Soc. Sci. Med. 1995;40(6):829-835.

⁹ Sorbi MJ, Maassen GH, Spierings EL. A time series analysis of daily hassles and mood changes in the 3 days before the migraine attack. Behav Med 1996;22:103-13.

¹⁰ Tulen JHM, Stronks DL, Bussmann JBJ, Pepplinkhuizen L, Passchier J. Towards an objective quantitative assessment of daily functioning in migraine patients: a feasibility study. Pain 2000;86:139-149.

¹¹ Leijdekkers MLA, Passchier J, Goudswaard P, Menges LJ, Orlebeke JF. Migraine patients cognitively impaired? Headache 1990;30:352-358.

asked to take part in a number of sessions of relaxation training away from home, each lasting about two hours, in order to study the efficacy of relaxation training as a means of treating people in this category.¹²

- Asking subjects to perform activities that cause unpleasant psychological or physical symptoms in the context of experiments in the field of clinical psychology. For example research into hyperventilation in which subjects with and without hyperventilation syndrome are asked to hyperventilate for a period, inducing symptoms such as anxiety, palpitations and dizziness.¹³

Generally speaking, much behavioural research, if considered from a different perspective, may be regarded as likely to advance medical science. Of the studies described above, those in the fields of clinical psychology, health psychology and medical psychology can most readily be placed under that heading. So might the example of psychometric testing cited: by testing a large group of subjects, standard data can be obtained, which can then be used in the determination of psychological abnormality. However, where some forms of behavioural research are concerned, it is hard to find a link with medical science. Such research should not in principle be considered to come within the scope of the WMO.

Examples of research for which WMO review is not required

- Research in the field of educational psychology into the effect of particular forms of education on subjects' ability to retain or apply knowledge and skills.
- Research in the field of testing and organisational psychology designed to support the development and evaluation of professional tests.
- Social psychology research into the circumstances under which prejudices find behavioural expression.
- Research in the fields of experimental psychology and social psychology into the process of falling in love.

Conclusion

On the basis of the considerations set out above, one must conclude that behavioural research can sometimes come within the scope of the WMO. Research in the fields of psycho-physiology, clinical psychology, health psychology and medical (child) psychology is most likely to require review in accordance the WMO, since it is mainly in the context of such research that subjects receive treatment or are asked to behave in a particular way (one the criteria set out in section 1 of the WMO for determining whether review is necessary). The studies cited above in any case appear to be potentially hazardous and/or onerous for subjects. Hence, WMO review would certainly seem appropriate.¹⁴

In this context, it is perhaps helpful to point out that section 16, subsection 2, of the WMO allows the appointment to a medical ethics review committee of people other than the experts referred to

¹² Larsson B, Melin L. The psychological treatment of recurrent headache in adolescents – short-term outcome and its prediction. *Headache* 1988;28:187-195.

¹³ Hornsveld H, Garssen B, Fiedeldij Dop M, Spiegel Pv. Symptom reporting during voluntary hyperventilation and mental load: implications for diagnosing hyperventilation syndrome. *J Psychosom Res* 1990;34:687-697.

¹⁴ Another problem that can arise in connection with research that is not subject to compulsory review is the absence of adequate safeguards or security arrangements for the careful storage and ultimate disposal of the (often personal) data. Such data needs to be processed with care even in the context of behavioural research that involves no burden and/or risk for the subject. A general, uniform solution for this problem should be sought through the development by the relevant professions of codes of conduct based on the Personal Data Protection Act.

in section 16, subsection 2, paragraph a, of the WMO. Furthermore, section 16, subsection 2, paragraph b, of the WMO requires that the constitution of a medical ethics review committee makes provision for consultation with other experts where necessary for the review of a given protocol.

It is therefore both possible and advisable to involve one or more experts in behavioural research in the review of behavioural research protocols, either by appointing them to the committee or by consulting them on an incidental basis (as laid down in the standing order of the committee).

CCMO, December 2001