

(irregular menses) and amenorrhoea (absent menses), this requires further investigation in randomised controlled trials (RCTs). The purpose of this study is to explore the feasibility of conducting a randomised clinical study involving CHM for PCOS in the United Kingdom (UK) and to pilot study procedures.

Methods: This is a prospective, practitioner and patient-blinded study that will randomise 40 PCOS patients with oligo- or amenorrhoea into 2 parallel groups, standardised CHM or individualised CHM, for 6 months. Community-based recruitment methods will include posters, flyers and social networking methods. Participants will be followed up at weeks 0 (baseline), 2, 4, 8, 12, 16, 20 and 24 (study close).

Scientific data for between group and within-participant analyses from baseline and Week 24 will be collected for menstrual regularity, the proposed primary outcome measure for the main study; and for secondary outcome measures of safety, body mass index, waist hip ratio, quality of life and hirsutism. This data will enable a sample size calculation for the primary outcome measure to be made for a main study. Feasibility study outcomes include suitability of proposed primary outcome measure, recruitment rate, consent rate by recruitment method, study visit attendance rate, compliance, and acceptability of interventions and study procedures such as completing questionnaires. Study procedures will be piloted such as randomisation, data collection and double-blinding. Feedback regarding study participation will be collected from patients via questionnaire and analysed qualitatively.

Results: Recruitment is due to start December 2012. Preliminary results in feasibility outcomes such as recruitment method generating highest consent rate, overall study consent rate and acceptability of the intervention will be presented.

Conclusions: At the end of this study, important feasibility data will have been gathered to determine whether an RCT can be conducted in this population in the UK. The potential for both standardised and individualised CHM will be explored and the study procedures piloted to inform the design of an adequately powered definitive RCT.

Workshop 17, Day 2, 12 Apr

3rd Parallel Sessions

14:45–16:15

Drama Studio

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The effect of a 3 months home use of cupping massage on chronic non-specific neck pain

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Objectives: Chronic nonspecific neck pain (CNP) is a disease of high economic importance. Latest research on cupping therapy has proven its efficacy in the treatment of CNP. Self-help techniques are becoming more and more important and cupping massage is regularly used by patients to ease their pain and improve general well-being. With this study we investigated the effect of a 3-month home use of cupping massage (CM) compared to progressive muscle relaxation (PMR) on neck pain, disability, well-being and pressure pain sensitivity in patients with CNP.

Methods: 84 patients with CNP were included into the study, 23 of them withdrew before randomization. After baseline assessment and subsequent randomization, 30 patients and partners were trained in CM, the other 31 were instructed in PMR. Both groups were asked to apply treatment twice weekly for 3 months. Outcomes included pain intensity (VAS, primary endpoint), pain related to movement (VAS), functional disability (NDI), well-being (FEW16), stress perception (PSQ20), quality of life (SF36), pressure pain threshold (PPT) at predefined neck muscles and adverse events (AE). Outcomes were analyzed using ANCOVA with post-treatment as dependent variable, group as classified factor, patients' expectations and respective baseline values as covariates.

Results: Patients were mainly female (74%) and 54.1±12.7 years on average. Baseline scores were comparable between the groups. Analyses revealed no group differences for pain intensity, however pre-post comparisons showed significant and clinically relevant improvements in both groups. No group differences were found for disability, stress perception and quality of life at 3 months, but for aspects of well-being and pressure pain thresholds. One serious and two slight AEs were observed, the serious AE however was not related to treatment.

Conclusions: Results of this study indicate that the home use CM is no more effective than the use of PMR. Results for well-being and PPT however suggest different modes of action of both techniques. Both techniques appear to be safe and well accepted by patients with chronic neck pain.

Workshop 13, Day 2, 12 Apr

2nd Parallel Sessions

11:30–12:45

Drama Studio

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The use of CAM therapies in Germany – a comprehensive analysis of population-based data since 2000

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Purpose: We aim to provide a comprehensive analysis of the use of major complementary therapies by the general adult population in Germany and its development since 2000.

Methods: Three different data sources have been used for our analyses: 1) original survey data from regular major population-based surveys on health care issues (Bertelsmann Gesundheitsmonitor; response rates between 65 and 72%; between 1500 and 1800 returned questionnaires) which repeatedly included questions on complementary therapies since 2002; 2) a systematic review of all available population-based surveys on complementary therapies in Germany since 2000; 3) publicly available data on health care provision and sales of herbal medicines.

Results: Data on the overall use of complementary therapies in Germany is somewhat inconsistent (ever use varying in the surveys between 63 and 86%, use in the last 12 months between 40 and 62%) and difficult to interpret as there is no single, clear definition or term covering the whole area. Data on the use of single therapies seem more reliable. The use of herbal medicine is particularly widespread in Germany but there is clear evidence of that the use is declining. In the Gesundheitsmonitor surveys the 12-month use varied until 2005 between 53 and 57%, while (after a change in reimbursement law) it dropped to 43% and 44% (two surveys) in 2006 and 40% in 2012. Analyses of pharmacy sales data confirm the abrupt drop after the legal change with a further slight trend of decline in the following years. The 12-month use of homeopathy varied between 15 and 20%, for acupuncture between 6 and 9%, for manual treatments (chiropractic and osteopathy) between 5 and 6%, for relaxation techniques between 7 and 10% without clear time trends. For traditional natural healing procedures (Kneipp therapies etc.) there seems to be a slight decline from 19 to 14%. The number of licensed non-medically qualified lay practitioners increased from 13,000 to 32,000 in 2010. The number of physicians holding so-called additional qualifications for complementary therapies accredited by the Germany Medical association increased, but in recent years the annual number of new additional qualifications tended to decrease slightly.

Conclusions: The use of complementary therapies is widespread in Germany. Physicians are the most important group of providers, but lay practitioners are gaining ground. The data suggest that overall the use of complementary therapies is no longer increasing and even declining for some therapies.