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A pilot randomised double blind controlled trial of the efficacy of purified fatty acids for the treatment of women with endometriosis-associated pain (PurFECT): study protocol.

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Abstract

BACKGROUND:

Endometriosis affects 6-10% of women and is associated with debilitating pelvic pain. It costs the UK > £2.8 billion per year in loss of productivity. Endometriosis can be managed by surgical excision or medically by ovarian suppression. However, ~ 75% symptoms recur after surgery and available medical treatments have undesirable side effects and are contraceptive. Omega-3 purified fatty acids (PUFA) have been shown in animal models to reduce factors that are thought to lead to endometriosis-associated pain, have minimal side effects, and no effects on fertility. This paper presents a protocol for a two-arm, pilot parallel randomised controlled trial (RCT) which aims to inform the planning of a future multicentre trial to evaluate the efficacy of Omega-3 PUFA in the management of endometriosis-associated pain in women.

METHODS:

The study will recruit women with endometriosis over a 12-month period in the National Health Service (NHS) Lothian, UK, and randomise them to 8 weeks of treatment with Omega-3 PUFA or comparator (olive oil). The primary objective is to assess recruitment and retention rates. The secondary objectives are to determine the effectiveness/acceptability to participants of the proposed methods of recruitment/randomisation/treatments/questionnaires, to inform the sample size calculation and to refine the research methodology for a future large randomised controlled trial. Response to treatment will be monitored by pain scores and questionnaires assessing physical and emotional function compared at baseline and 8 weeks.

DISCUSSION:

We recognise that there may be potential difficulties in mounting a large randomised controlled trial for endometriosis to assess Omega-3 PUFA because they are a dietary supplement readily available over the counter and already used by women with endometriosis. We have therefore designed this pilot study to assess practical feasibility and following the 'Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials' recommendations for the design of chronic pain trials.