

Dietary intake in women with Fibromyalgia compared to healthy women?

# **Participant information sheet**

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#### 1. Background

Fibromyalgia is a condition which affects up to 1.76 million people in the UK and is most common in women aged between 30 and 60 years. It is characterised by widespread pain and fatigue, having a detrimental effect on day to day functioning. Previous studies have focused on the body composition and nutritional deficiencies in fibromyalgia patients. However, no previous study has used a diet diary as a form of assessment. This is an important omission as diet diaries are known to give more accurate estimates of food intake than some other dietary assessment methods. This project will use a four day diet diary and a symptom questionnaire to assess for differences in dietary intake between women with fibromyalgia and women without fibromyalgia.

#### YOU CAN TAKE PART IN THIS STUDY IF YOU:

- > Are female
- ➤ Either have a diagnosis of fibromyalgia from your health professional (for fibromyalgia study group) OR consider yourself to be free from fibromyalgia (for control study group.)

# YOU CANNOT TAKE PART IN THIS STUDY IF YOU:

- Have a personal history of lupus, rheumatoid arthritis, multiple sclerosis, or epilepsy.
- ➤ Have self-diagnosis (not by a health professional) of fibromyalgia
- ➤ Have a history of psychiatric disorders.
- ➤ Have a history of drug or alcohol abuse.
- Take part in shift work.

#### 2. Preliminary

#### **Screening**

As part of the screening process, you will be asked to answer a screening questionnaire to determine your general health status and to assess your suitability to participate in the study. Depending on the results of your screening evaluation, you may then be eligible to participate. All information obtained will be restricted to the investigators only and will be kept strictly confidential.



#### Information to be completed

Eligible participants will complete a consent form, a four day diet diary and an impact questionnaire. The impact questionnaire will focus on pain and difficulty during daily life over a seven day period. It is required that participants complete all questions regardless of whether pain has occurred. If possible, the diet diary should be completed for 2 weekend day and 2 weekdays. Instruction on completing the documents will be provided. These will be posted to participants and returned to investigators upon completion with the pre-paid envelope provided. The completion of these will be undertaken by participants without the investigator present.

## 3. Expected timeframe of study

The diet diary will be completed over four days for all food and fluid consumed. The impact questionnaire needs to be completed once. This questionnaire will take approximately five minutes to complete, and it will reflect the previous seven days. Upon the return of all diet diaries and questionnaires, they will be analysed and the whole group results (i.e. an average result from all Fibromyalgia participants, and all control participants) will be provided to Fibromyalgia UK, as well as being published in scientific journals.

#### 4. Number of applicants expected to participate

It is estimated that 15 women with fibromyalgia and 15 women without fibromyalgia will participate. It will be aimed that participants in both groups will be matched for age.

## 5. General

All individual participant information and results obtained from this study will be restricted to the investigators only and will be kept strictly confidential. You will be free to withdraw from the study at any time, without needing to justify your decision but your information will be kept by the University of Surrey.

This study has received a favourable opinion from the faculty of Health and Medical Sciences Ethics committee.

#### 6. Contact details

If you should have any questions regarding any aspect of this study, please contact:

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