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Study protocol

The effects of Ramadan fasting on physical and mental health in healthy adult Muslims—Study protocol for a randomised controlled trial

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ABSTRACT

Introduction: Fasting during the month of Ramadan is considered one of the five pillars of the Islamic religion, and Muslims must abstain from food and drink between dusk and dawn. Research has found that fasting during Ramadan may affect the health of Muslims. Results of those studies however are often contradictory, with quantity and composition of meals during Ramadan being potential influencing factors. In order to determine its influence on the outcomes after Ramadan fasting, this study aims to determine whether a modified healthy fasting regimen is beneficial for physical and mental health among adult Muslims.

Design, methods and analysis: This is a randomised controlled trial with two parallel groups testing the superiority a modified fasting regimen compared to usual fasting during Ramadan. Healthy adult Muslims between 18 and 60 years of age, who plan to participate in Ramadan fasting, will be randomly allocated to one of two groups with a 1:1 allocation ratio. The intervention group will receive additional health advice regarding behavioural and nutritional modifications during Ramadan, the control group will conduct the Ramadan fasting as usual. Before, at the end of the Ramadan period and 12 weeks later data will be collected on participants mental and physical well-being, including quality of life (WHO-5, primary outcome), sleep quality, spirituality, mindfulness, body constitution (weight, body mass index, body fat, waist circumference, hip circumference), blood pressure and heart rate, blood lipid and glucose levels, liver enzymes, uric acid and creatinine, and adverse events.

Discussion: The trial will provide evidence if and to what extend behavioural and nutritional modifications might be beneficial for healthy Muslims undergoing Ramadan fasting. If successful this intervention might provide a valuable approach to improve the health and well-being during Ramadan fasting.

Ethics and trial registration: The trial protocol has been reviewed and approved by the Ethics Committee of the Medical Faculty of the University of Duisburg-Essen (approval number 15-6336-BO), and it is registered at ClinicalTrials.gov (Identifier: NCT02775175).

1. Introduction

1.1. Background and rationale

Fasting during the month of Ramadan is considered one of the five pillars of the Islamic religion, and a compulsory act for all sane, healthy Muslim adults [1]. Muslims must abstain from food and drink between dusk and dawn, and they are encouraged to increase offerings of prayers, to focus on the basic essentials in their life and to refrain from sinful behaviours [1].

Since the Islamic calendar is a lunar calendar, Ramadan migrates throughout the seasons, and the 2016 Ramadan will be carried out around summer solstice in Germany making it one of the most challenging fasting periods for Muslims in Germany.

In medical terms Ramadan fasting can be considered intermittent fasting, with extended periods of food and drink abstinence per day. While medical fasting itself has been considered beneficial

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for disease prevention and for chronic diseases [2,3], the effects of Ramadan fasting are rather inconclusive, as studies have found positive as well as negative effects on body composition, blood lipids and glucose levels [4–9]. Different explanations for such contradictory results are possible, including the season during which the Ramadan is conducted, the climate zone, and the sample characteristics. The quantity and composition of meals during Ramadan might also differ substantially between the study participants, and contribute to conflicting evidence [10]. Subjective parameters including not only well-being and satisfaction, but also spirituality, have not even been investigated. It is also difficult to interpret results from Ramadan trials correctly since they were usually conducted without a control group. While it is obviously impossible to randomise Muslims to whether they fast during Ramadan or not, one solution might be to modify the fasting regimen in accordance with religious rules, and to determine whether a fasting focused on health and well-being might be superior compared to an unaltered fasting regimen.

This is the first randomised controlled trial examining the effect of two different Ramadan fasting regimens on well-being and health in healthy adult Muslims. It is also the first trial examining quality of life, mental well-being and spirituality systematically in a cohort of male and female Muslims undergoing fasting during Ramadan.

1.2. Objectives

This study aims to determine whether a modified healthy fasting regimen is beneficial for physical and mental health among adult Muslims undergoing Ramadan in Germany in 2016.

1.3. Trial design

The trial is designed as a randomised controlled trial with two parallel groups with 1:1 allocation ratio testing the superiority of one fasting regimen against another.

2. Methods and analysis

2.1. Participants, interventions and outcomes

2.1.1. Study setting

The study trial site is the Department of Internal and Integrative Medicine, Kliniken Essen-Mitte, a teaching hospital of the University Medical Hospital Essen, in Essen, Germany. The trial will be conducted between June and November 2016 in the outpatient clinic of the department. Trial participants will be recruited externally via advertisement in Muslim community centres in Essen and surroundings. After a telephone screening, eligible subjects will be invited for further assessment by the study physician, who will provide them with detailed study information, and after obtaining their informed consent, will check subjects medical history, determine their health status and decide whether they can be included in the trial.

2.1.2. Eligibility criteria

In order to be included in the trial, subjects have to be aged between 18 and 60 years, and physically and mentally capable of fasting during Ramadan. Only those subjects will be included who plan to participate in the 2016 Ramadan, and who are not undergoing Ramadan fasting for the first time.

Exclusion criteria are untreated or malignant hypertension, severe psychological conditions (depression, schizophrenia, and addiction), and severe comorbid disorders such as diabetes mellitus, cancer without remission, and rheumatologic diseases. Furthermore women during pregnancy or breast feeding will be excluded, as will subjects with eating disorders, current dieting, or those with a body mass index below 20 or higher than 40 kg/m^2.

2.1.3. Interventions

The *experimental group* will receive a specific guide for a healthy Ramadan fasting. The booklet contains information about the background of Ramadan, the influence of fasting on physical and mental health in general, and potential behavioural and nutritional modifications that might be beneficial for the health and well-being. It will also contain recipes for healthy meals during Ramadan.

The advice is partially based on advice from *Communities in Action* who have published a brochure entitled *Ramadan Health Guide—A Guide to Healthy Fasting* with support of the National Health Services (NHS) in the UK [11]. In a nutshell, we will ask participants to be mindful about their behaviour and diet during Ramadan. In terms of diet they are asked to reflect on the quantity and quality of food and to replace unhealthy food by alternative healthy food choices. They are asked to reduce the amount of sweet, fatty and very spicy food, and to switch to a balanced diet with lots of vegetables and fruits, to replace sweet drinks by water and tea, and to use wholefood alternatives and wholemeal products.

The intervention consists of educational advice only, and we contained ourselves from designing an intervention with compulsory components as we agreed that this would potentially result in reduced compliance among participants. We decided that it would be best if participants could pick the advice from the booklet that would suit them and their lifestyle.

The *control group* will continue with their usual Ramadan diet and activities without modifications. They will be provided with the advice after the follow-up measurement.

2.1.4. Incentives

In order to keep study participants motivated gift certificates for recreational activities will be raffled via a lottery.

2.1.5. Outcomes

We will collect sociodemographic, anthropometric, and questionnaire data and haemal markers. Sociodemographic data will include information on age, gender, family status, highest education and employment status.

Anthropometric data will include height, weight, body fat, waist circumference, hip circumference, blood pressure, and heart rate. Waist circumference will be measured by two research assistants with a measuring tape positioned in the horizontal plane exactly midway between the iliac crest and the costal arch, using the mean score of two consecutive measurements only if the measures did not differ more than 1 cm [12]. Hip circumference will be measured in the horizontal plain at the maximal circumference of the hips or buttock region above the gluteal fold, whichever is larger. Again two consecutive measurements will be averaged. Weight and body composition (body fat percentage) will be determined using a standard bioelectrical impedance device (BF 511, OMRON Healthcare, Mannheim, Germany). Blood pressure and heart rate will be determined using a standard automated digital blood pressure monitor on the side with the higher blood pressure values, calculating the arithmetic mean of two consecutive measurements.

The following questionnaires will be used to determine health and well-being: The *WHO-5 Well-Being Index* will serve as a measure for quality of life [13,14]. The instrument is suitable for subjects without health-related impairments, and includes five items related to positive mood, vitality, and general interests in life rated on a 6-point Likert scale each. The 10-item *BMLSS-10* (*Brief Multidimensional Life Satisfaction Scale*) will be used to measure satisfaction with life [15]. This one-factorial item instrument measures satisfaction in five domains: intrinsic (myself, overall life), social (friendships, family life), external (work, where I live),