

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).

Keywords

Ramadan; fasting; Religious health

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1. INTRODUCTION

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 adults¹. 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 behaviours¹.

Since the Islamic calendar is a lunar calendar, Ramadan migrates throughout the seasons, and the 2016's 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 for disease prevention and for chronic diseases^{2,3}, the effects of Ramadan fasting are only short term and rather inconclusive, as studies have found positive as well as negative effects on body composition, blood lipids and glucose levels⁴⁻⁹. 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 evidence¹⁰. 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.

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 2016.

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.

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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.

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 a brochure of *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 UK¹¹. 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 cm¹². 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 life¹⁵. This one-factorial item instrument measures satisfaction in five domains: intrinsic (myself, overall life), social (friendships, family life), external (work, where I

live), perspective (financial situation, future prospects), and health-related satisfaction (health situation, ability to cope). The *SpREUK-P SF17 (Spiritual and Religious Attitudes in Dealing with Illness – Frequency of Engagement in Spiritual Practices)*¹⁶ will be used to examine the frequencies of a large spectrum of organized and private religious, spiritual, existential and pro-social-humanistic practices. All 17 Items are scored on a 4-point Likert scale, examining the frequency of spiritual practices in daily life. The *PROMIS™ (Patient-Reported Outcomes Measurement Information System) Sleep Disturbances* and the *Sleep related Impairments* will be used to assess sleep quality and sleep disorders with 8 items each¹⁷. The 10-item *CPSC questionnaire (Conscious Presence and Self Control)*¹⁸ will be used to determine the level of 'daily life mindfulness' or situational awareness. Meaning, peace and dimensions of a person's spirituality will be assessed using the *FACIT-Sp (Functional Assessment of Chronic Illness Therapy - Spiritual Well-Being Scale)*, which is comprised of 12 items¹⁹. Finally ease of life will be examined using the 10-Item *ePLC scale (Emotional Scale for Positive Life Construction, Contentedness, Well-being)* from the *ERDA (Emotional/Rational Disease Acceptance)* questionnaire²⁰.

The following instruments will be applied at baseline only to control for possible confounding variables: The *DSES (Daily Spiritual Experience Scale)* to determine a person's perception of the transcendence in daily life, which may reflect their general level of spirituality^{21,22}; the *DUREL (Duke University Religion Index)* to examine organized and non-organized religious activities and intrinsic religiosity, which is used as a measure of religiosity²³; and questions on current lifestyle factors such as smoking, alcohol consumption, exercise activity levels, and dieting behaviours. Lastly the motivation to participate in Ramadan fasting will be measured; and subjects can choose from a list of options, and open space is provided to list other reasons if necessary.

The following haemal markers will be identified using serum samples: Metabolic markers such as triglycerides, cholesterol, HDL and LDL cholesterol, fasting glucose, AST (aspartate aminotransferase), ALT (Alanine aminotransferase) and GGT (gamma-glutamyltransferase), uric acid and creatinine. All haemal markers will be determined by a certified laboratory (Zentrum für Labormedizin und Mikrobiologie GmbH, Essen, Germany; Accreditation according to DIN EN ISO 15189 and DIN EN 17025).

2.1.6. Primary outcome

Primary outcome will be quality of life according to the WHO-5 Well-Being Index at the post Ramadan assessment (week 4). All other outcomes are defined as secondary outcomes.

2.1.7. Assessment of adherence

Participants will be asked to describe a typical Ramadan night meal during the study, and indicate to what degree they adhered to the advice given (in percent). They will further be asked which of the advice they felt was most suitable, and whether they followed it.

Participants in both groups will also be asked to indicate whether they have amended their usual fasting diet during the study period.

2.1.8. Assessment of safety

All adverse events, i.e. any untoward medical occurrence, or abnormal serum marker will be recorded and assessed by the study physician. All participants will further be asked about any such event during the Ramadan period at the post-intervention assessment.

2.1.9. Participant timeline

Subjects will be invited for a pre-study visit to determine their eligibility for the trial one to two weeks before the trial. At this visit they will be provided with detailed study information, and after obtaining their informed consent, the study physician will check the subject's medical history, determine their current health status including their blood pressure and body mass index, and decide whether they are included in the trial. If they are included in the trial appointments for subsequent measurements will be made. Measurements will be conducted at week 0 (baseline-assessment), week 4 (post Ramadan assessment) and week 16 (follow-up-assessment). The assessments at week 4 will be conducted in the evening shortly before fast breaking, while the other measurements will be conducted in the morning. This was necessary to ensure that participants were still fasting when blood samples were taken. An overview of time points and measurements is presented in table 1.

2.1.10. Sample size

No previous data are available to estimate what effect size we can expect. Using G*Power Software²⁴ we base our sample size on the following deliberation. In order to detect a moderate group difference on any given outcome (effect size Cohen's $d=0.5$), 51 subjects per group will be sufficient using a one-sided t-test with a significance level of $\alpha=0.05$ and a power of $1-\beta=0.80$. Accounting for a loss of power due to a maximum of 10% dropouts, we plan to include 57 subjects per group, i.e. the anticipated total sample size will be 114.

2.1.11. Recruitment

Trial participants will be recruited from externally via advertisement in Muslim community centres in the city of Essen and surroundings. After a telephone screening, eligible subjects will be invited for further assessment by the study physician.

2.2. Assignment of interventions

2.2.1. Randomization

Participants will be randomly assigned to either experimental or control group with a 1:1 allocation using the Random Allocation Software²⁵. The randomisation will be stratified by gender, and be conducted in blocks of randomly varying block lengths.

The randomisation list will be created by the study coordinator who is not involved in participant recruitment or assessment. Only the study coordinator will have access to the list. Based on that list the study coordinator will prepare sequentially numbered, opaque, sealed envelopes containing the intervention assignments. After obtaining written informed consent and baseline assessment, the study physician will open the lowest numbered envelope to reveal that subject's assignment, inform the subject about the assignment, and file a record. The study physician will not be involved in the measurements.

2.2.2. Blinding

Participants cannot be blinded to the intervention because following the additional health advice during Ramadan requires an active engagement of the participants. Nevertheless outcome assessors will be blinded to group assignment when handing out/collecting the questionnaires, taking the physical measurements (weight, waist and hip ratio, body fat percentage, and taking serum samples); and the laboratories will not receive any information on the subject's trial assignment while analysing haemal markers.

2.3. Data collection, management, and analysis

2.3.1. Data collection methods

Questionnaire data will be collected using paper and pencil. All questionnaires will be provided in German, and all questionnaires will be checked immediately after completion by the outcome assessors, and missing or unclear answers will be discussed with the participant. Anthropomorphic measures will be recorded on measuring protocol forms by the assessors during measurement. Blood markers will be documented by the laboratory, and the laboratory findings will be collected to the assessors, and filed under the respective participant's number.

2.3.2. Data management

Data will be stored at the department, in a secure space; and only the assessors and the study coordinator will have access to the data. Personal data will be stored separately, and all records, questionnaires and laboratory findings will be identified by the participants' study IDs. All data will be entered into a SPSS file (IBM SPSS Statistics for Windows, release 22.0. Armonk, NY: IBM Corp). The study coordinator will prepare the file, and train the assessors on data entry. Correct data entry will be ensured by two assessors processing the data separately. Data will be stored locally in a password encrypted folder, and only the participants' study IDs will be used as an identifier within the file.

2.3.3. Statistical methods

All analyses will be conducted on the intention-to-treat population, i.e. every subject providing baseline data will be included in the final analysis. Missing values will be replaced using multiple imputation technique. Using SPSS 50 new datasets will be generated for each missing value, and the average will be used to replace missing values.

Primary outcome will be quality of life according to the WHO-5 Well-Being Index at the post Ramadan assessment (week 4). All other outcomes are defined as secondary outcomes.

Outcomes will be analysed using an ANCOVA (Analysis of Covariance), with group serving as classified variable; and gender, age, baseline values and confounding variables as covariates. Categorical data will be analysed using Chi-square tests. Correlational analysis will further be conducted to determine associations between outcomes.

2.4. Monitoring

2.4.1. Data monitoring

The study is investigator initiated, and as such no competing interests exist for the investigators. No external data monitoring committee (DMC) will be incorporated in the study.

2.4.2. Harms

All adverse events, i.e. any untoward medical occurrence, or abnormal serum marker will be recorded during the study. All participants will be asked explicitly about any such event during the Ramadan period at the post Ramadan assessment. All adverse events will be assessed by the study physician and the study coordinator, and treatment will be initiated if necessary.

3. ETHICS AND DISSEMINATION

3.1. Research ethics approval

The trial protocol (Version 4, 15/05/2016) 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 registered at ClinicalTrials.gov (Identifier: NCT02775175). The study will be conducted according to common standard guidelines for clinical trials (Declaration of Helsinki, and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and Good Clinical Practice (ICH-GCP) revised version, Somerset West, Republic of South Africa, 1996).

3.2. Consent or assent

Oral and written informed consent will be obtained by the study physician at the assessment visit, after providing interested subjects with detailed information about the study, its aims, methods and procedures.

3.3. Confidentiality

Personal information about potential and enrolled participants will be stored in a secure location for a maximum of 10 years, and not be used for purposes outside this trial. All data will be key-coded introducing a participant specific numerical ID code to ensure privacy, and confidentiality of personal information of the participants. Published data will not contain any information or hints on the participant's identity.

3.4. Declaration of interests

No financial or other competing interests exist.

3.5. Access to data

The assessors and the study coordinator will have access to the data during the trial. Only the principle investigator and the study coordinator will have access to the final trial dataset. No contractual agreements limiting access for investigators exist.

3.6. Dissemination policy

Data from the trial will be submitted for publication in a peer-reviewed scientific journal, as well as presented at national/international conferences. The authors intend to provide trial participants, and the press with summaries of the trial results. Data will not be shared in public repositories; researchers interested in the data may contact the investigators for access to participant-level datasets.

TRIAL STATUS

Recruitment was started in May 2016.

AUTHORS' CONTRIBUTIONS

Conceived and designed the study: RL, HC, PK, JA, TR, GD, IF, CS, AB. Drafted the manuscript: RL. All authors read and approved the final version of the manuscript.

FUNDING STATEMENT

No external funding was received for this study.

ACKNOWLEDGEMENT

The authors are grateful to Dr. Abdullah M. AlBedah and Dr. Mohamed Khalil from the National Center for Complementary and Alternative Medicine, Ministry of Health, Riyadh, Kingdom of Saudi-Arabia, and Prof. Dr. Andreas Michalsen, Charité-University Medical Center, Berlin, Germany for their advice during development of the trial protocol. The authors would also like to thank Annette Tengemann, and the involved clinic staff for their on-site trial support.

COMPETING INTERESTS STATEMENT

No financial interests are reported by the authors.

TABLES

Table 1: Overview of measures and measurement time points

Item	Pre-study visit	Baseline	Post Ramadan	Follow- Up
	Week -2	Week 0	Week 4	Week 16
Informed consent	x			
Sociodemographic characteristics	x			
Spirituality/ Transcendence perception (DSES)		x		
Religiosity (DUREL)		x		
Motivation for Ramadan fasting		x		
Lifestyle: Smoking, alcohol, exercise activity, dieting		x		
Quality of life (WHO-5)		x	x	x
Satisfaction with life (BMLSS-10)		x	x	x
Engagement in spiritual practices (SpREUK-P SF17)		x	x	x
Mindfulness/situational awareness (CPSC)		x	x	x
Spiritual well-being (FACIT-Sp)		x	x	x
Ease of life (ePLC scale, ERDA)		x	x	x
Sleep disturbances/sleep-related impairments (PROMIS™)		x	x	x
Adherence			x	
Height, in m	x			
Weight, in kg	x	x	x	x
BMI, in kg ² /m	x	x	x	x
Blood pressure, in mmHg	x	x	x	x
Heart rate, in bpm	x	x	x	x
Waist circumference, in cm		x	x	x
Hip circumference, in cm		x	x	x
Triglycerides		x	x	
Cholesterol		x	x	
HDL cholesterol		x	x	
LDL cholesterol		x	x	
Fasting glucose		x	x	
AST		x	x	
ALT		x	x	
GGT		x	x	
Uric acid		x	x	
Creatinine		x	x	
Safety		x	x	

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