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Ready-To-Go Project – Development and verification of a travel medical questionnaire

Submission date
02/11/2020

Recruitment status
No longer recruiting

Registration date
05/11/2020

Overall study status
Completed

Last Edited
09/03/2022

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
This project aims to develop and verify a travel medical questionnaire designed to assess the risk of falling ill while travelling abroad. Travellers are exposed to an increased risk of developing medical conditions linked to various risk factors such as their travel destination, travel duration, travel purpose and their health condition. The Ready-To-Go questionnaire, which was developed in collaboration with a travel medical expert group, assesses all the aforementioned risk factors. The questionnaire is intended to be filled out by travellers as medical preparation before their departure. Four risk categories result from the questionnaire according to travellers' risk of falling ill during their journey. The risk category emerging from the questionnaire will help travellers and medical professionals to decide if a pre-travel health consultation at a specialized Travel Clinic is necessary. Furthermore, the Ready-To-Go questionnaire can serve as a link between travel medical health care and primary health care.

To verify the accuracy of this questionnaire, customers scheduled for a pre-travel health consultation at the Travel Clinic of the University of Zurich will be asked to complete the questionnaire.

The aims of this study are to develop a medical pre-travel triage questionnaire to objectify travellers' health risk, to assess the questionnaire's feasibility in a travel medical setting, and to validate the Ready-To-Go questionnaire risk categories by comparing their correlation to the risk assessment by pre-travel health consultants, to the destination-specific indication of anti-malaria medication, and of yellow fever vaccination respectively.

Who can participate?
Adults over the age of 18 years who attend the Travel Clinic of the University of Zurich for a pre-travel health consultation. Furthermore, participants must be fluent in either English or German.

What does the study involve?
Participants in the Ready-To-Go project will be asked to fill out the Ready-To-Go questionnaire to the best of their knowledge before their pre-travel health consultation at the Travel Clinic of the University of Zurich. There are no other requirements.

What are the possible benefits and risks of participating?
There will be no immediate benefit to those taking part in the Ready-To-Go project. However, the participation in this project could result in the widespread use of the Ready-To-Go questionnaire and therefore benefit future travellers. Participants are not exposed to any health risks by participating in this project.

Where is the study run from?
The Epidemiology, Biostatistics and Prevention Institute of the University of Zurich (Switzerland). The recruitment of study participants takes place at the affiliated Travel Clinic.

When is the study starting and how long is it expected to run for?
From January 2020 to December 2020 (updated 01/06/2021, previously: January 2021)

Who is funding the study?
The University of Zurich (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Development and validation of a medical pre-travel triage questionnaire: Ready-To-Go Questionnaire

Acronym
Ready-To-Go

Study objectives
Travelers who are assigned a high-risk category according to the Ready-To-Go questionnaire are more likely to be assessed as high-risk travelers by pre-travel health consultants and are more likely to travel to a destination with an indication for anti-malaria medication or yellow fever vaccination respectively and therefore require a specialised pre-travel health consultation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/10/2020, Ethics Committee Zurich (Stampfenbachstrasse 12, 8090 Zürich, Switzerland; +41 43 259 79 70; info.kek-@kek.zh.ch), ref: 2020-02109

Study design
Single-centre observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
See additional file ISRCTN10172086_PIS_english_v2.2, 03.10.2020 (added 02/12/2020)

Health condition(s) or problem(s) studied
Encounter for health counseling related to travel, prevention of medical conditions in travelers

Interventions
Over a period of time of three months, participants will be enrolled in this study will be asked to fill out the Ready-To-Go questionnaire prior to their pre-travel health consultation at the Travel Clinic of the University of Zurich. The Ready-To-Go questionnaire and its scoring algorithm were developed in collaboration with an expert panel comprising two senior travel medical experts and two senior physicians working in Travel Clinics. The questionnaire's items can be broadly divided into questions on travelers' itinerary (travel destination, travel duration, travel purpose) and questions on their health status (pre-existing medical conditions, current medication, allergies, undesirable reactions to vaccinations, pregnancy or breastfeeding).

There are no further requirements to be fulfilled by study participants.

Intervention Type
Other

Primary outcome measure
1. Risk assessment by the pre-travel health consultant using four categories the Ready-To-Go questionnaire at baseline and validated by the assigned consultant after the pre-travel health consultation
2. Destination-specific indication for anti-malaria medication using a yes/no question in the Ready-To-Go questionnaire at baseline and validated by the assigned consultant after the pre-travel health consultation
3. Destination-specific indication for yellow fever vaccination regardless of the participants' vaccination status using a yes/no question in the Ready-To-Go questionnaire at baseline and validated by the assigned consultant after the pre-travel health consultation

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/01/2020

Completion date
31/12/2020

Eligibility

Key inclusion criteria

1. Travel clinic customer scheduled for a pre-travel health consultation
2. Age ≥18 years
3. Fluent in either German or English

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
1. No informed consent provided

Date of first enrolment
01/11/2020

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Switzerland

Study participating centre
Travel Clinic, Epidemiology, Biostatistics and Prevention Institute
University of Zurich
Hirschengraben 84
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Sponsor information

Organisation
University of Zurich

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Epidemiology, Biostatistics and Prevention Institute
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Sponsor type
University/education

Website
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ROR
https://ror.org/02crff812

Funder(s)

Funder type
University/education

Funder Name
Universität Zürich

Alternative Name(s)
University of Zurich, Switzerland, University of Zurich, UZH

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/08/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are/will be available upon request and approval from the Sponsor of this study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2.2	03/10/2020	02/12/2020	No	Yes
Results article		05/03/2022	09/03/2022	Yes	No