PARTICIPANT INFORMATION SHEET

The GlyCarb Remote Study

Measuring postprandial Glycaemic responses to Carbohydrate-rich meals using a standardised remote monitoring protocol

Short title: GlyCarb Remote Study

You are being invited to take part in a research study run by the Quadram Institute Bioscience (QIB). Before you decide to take part, it is important for you to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully and discuss it with others if you wish.

Part 1 of this information sheet tells you the purpose of the study and what will happen if you decide to take part.

Part 2 gives you more detailed information about how of the study will be conducted.

Please ask if there is anything contained in the information sheet that is not clear, or if you would like more information.
Take time to decide whether or not you would like to take part.
This information is yours to keep.
Thank you for reading this.

Study contact details:

glycarb@quadram.ac.uk

https://quadram.ac.uk/glycarbstudy/

Part 1

What is the purpose of the study?

Dietary carbohydrates are an important source of energy and the main component of many staples, such as bread. Ingestion and digestion of carbohydrates is accompanied by an increase in blood sugar. Foods that contain the same amount of carbohydrate can have different effects on our blood sugar after ingestion. A high consumption of carbohydrate rich foods that are quickly digested can increase the risk of developing illnesses such as cardiovascular disease and type 2 diabetes. It is therefore recommended that our total daily carbohydrate intake comes mostly from foods that are more slowly digested.

There are many factors that affect our blood sugar in response to a carbohydrate meal. This can include: how the food is processed (e.g. whether it is ground or milled, or exposed to liquid or heat); the rate at which we digest the starch component of the carbohydrate (e.g. slowly digested starch or resistant starch results in a lower blood sugar response); and other components of the meal in which the carbohydrate is consumed (e.g. whether it also contains protein, fat and fibre).

At the Quadram Institute Bioscience we are looking at the ways by which carbohydrate foods are digested and broken down in the body. In doing so, we will contribute to the development of new food products that may be beneficial to health. We therefore wish to investigate a range of carbohydrate rich test meals (from off the supermarket shelf through to those we have re-formulated) on blood sugar after ingestion.

What does the study involve?

GlyCarb consists of a series of studies taking place following the same standard protocol. This means that while the type of food to be consumed may change, all study activities are repeated the same way, for all GlyCarb studies. You will take part in one study at a time, it is up to you to decide if to take part in other GlyCarb studies, in the future. During each study, you will consume four carbohydrate-rich meals for breakfast (first meal of the day) on set days, over a 2-week period of continuous glucose monitoring. You will be informed before starting the study about which food types you will be consuming, if you decide to take part.

Glucose monitoring involves wearing a sensor (a continuous glucose monitor) on the back of your arm.
The device will measure your body sugar levels. You will need to scan the device every 6-8 h using the *LibreLink* smartphone app.
There will be some short online forms with questions about the meal and your hunger/fullness levels. You will be asked to avoid alcohol and high calorie meals (1000 kcal or more) in the evening before each test meal, and to fast for 12 h but drink plenty of water before eating each test meal.

Participation is from home. The study does not require any visits to a research facility. The study team will use video calls, e-mails and messages to guide you through the process. All materials required will be delivered to you, all postage costs will be covered by the study.
See also '*What will happen to me if I do take part', page 5* for more details.

Why have I been invited?

You have received this information because you have either (i) responded to an advertisement about the study (ii) been identified as a potentially suitable candidate from the participant database held at the Quadram Institute Bioscience.

We are aiming to recruit healthy individuals, aged 18 years or over who are willing to consume the study foods, and have an HbA1C (blood sugar) level below 42 mmol/mol and a Body Mass Index (BMI) between 18 and 30 kg/m^2.

You must also have access to or own a smartphone and/or a tablet or a computer and be willing to use this for the study.

You will not be able to participate if you:

- are a smoker (or stopped smoking less than 6 months ago) of tobacco or electronic cigarettes
- are taking prescribed or non-prescribed medication that may affect the study outcome or your well-being if you took part e.g., warfarin or proton pump inhibitors (we will advise you accordingly)
- active infection with COVID-19 (if so, we may ask you to postpone screening until after the self-isolation period or 10 days from the positive test result or symptoms)
- have a medical condition that may affect the study outcome or your well- being if you took part e.g., gastro- intestinal disease, active cancer, haemophilia (we will advise you accordingly)
- take supplements judged to affect the study data e.g., protein shakes or supplements containing ascorbic acid that are not taken consistently (we will advise you accordingly).
- you have a known allergy, intolerance or sensitivity to any food products or adhesives
- are following a restrictive diet that may affect the study outcome
- are pregnant or have been pregnant within the last 12 months
- are related to someone in the study team (e.g., spouse, partner, immediate family member) or are line managed by the Chief Investigator
- are currently involved in a study that involves dietary intervention.
- the results of our screening test indicate that you are not suitable to take part in this study
- are unable to provide written informed consent

Do I have to take part?

It is up to you to decide. We will describe the study in this information sheet. If, after reading it, you are interested in taking part in the study, you should contact the research team via email to GlyCarb@quadram.ac.uk

Please feel free to say no by not responding to this information. Do not worry, nobody will contact you to try and persuade you to join the study.

After you have replied to tell us you are interested in participating, a member of the study team will contact you, and you will be invited for a talk with the study scientist/manager. This can be via Zoom video call or over the telephone. An expression of interest does not commit you to taking part.

If you are on the Quadram Institute Bioscience participant database, a decision to withdraw or not to take part will not affect your participation in future studies.

What will happen to me if I do take part?

If you decide to take part, your involvement will last about 1 month during which time you will consume four foods that were descried to you during the study talk. Once you have completed all foods and questionnaires assigned to you, your study participation will be completed. For an overview see Figure 1.

You may be able to participate in other GlyCarb-Remote studies, if you are interested in taking part, you will need to contact the research team again to express your interest. New GlyCarb studies will be listed on the website when available.

This study has been designed to maintain social distancing and thereby reduce risk of COVID-19 transmission between participants and researchers during the ongoing outbreak. All study appointments will be

'virtual' – meaning that you will speak with the study team using a video call, rather than meeting in person. Each of these appointments is described below.

For video call, Zoom will be used. You do not need to download Zoom or to make an account to take part in the study, a link to join the videocall will be provided to you via email by the study team. If you decide to make an account, please be aware of the Zoom terms and conditions when subscribing.

If at any point during the study, you or someone in your household develop symptoms of coronavirus (COVID-19) infection and/or test positive for coronavirus (COVID-19) and/or come in contact with someone who has coronavirus and are told to self-isolate (NHS test and trace service advises you to do so), you will be asked to withdraw from the study, if study activities cannot be rescheduled. Once 10 days have elapsed from the positive test result or symptoms development, you will be invited to re-start the study, if you wish to do so.

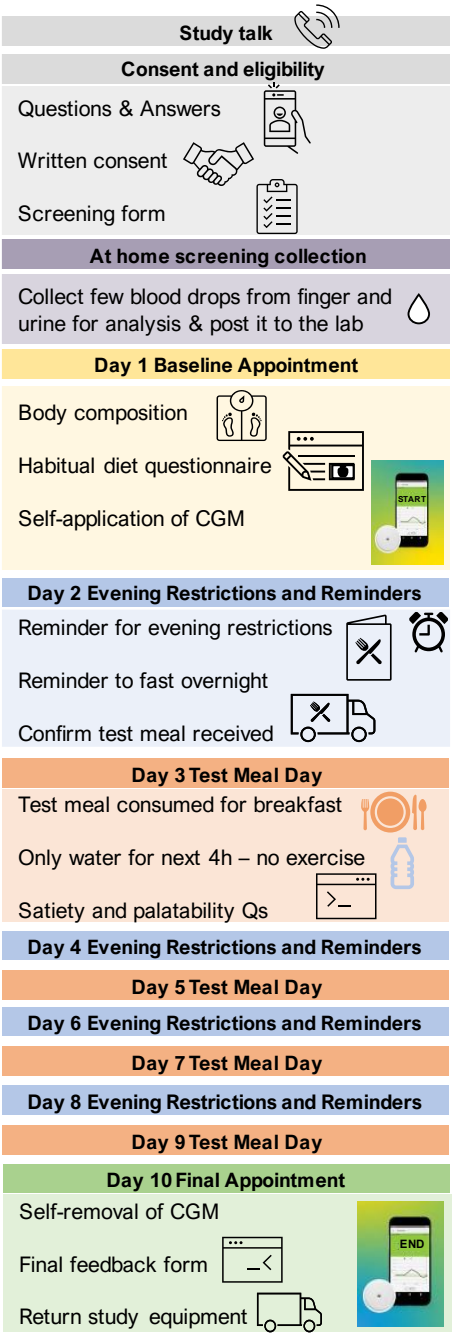

Figure 1. Study diagram.

Successful application of the CGM marks Day 1 of the study period. **The sensor must be scanned every 6 to 8 h.**

In some cases, meal consumption can be postponed to a different day. This date may fall on a day with an 'even number' between test days, provided that you are able to follow the evening dietary restrictions.

Therefore, the study duration may be up to 14 days during which, CGM will be worn continuously.

► **Study talk** *(Virtual Appointment, 1 h)*

This talk will last for about one hour. A member of the research team will go through this information sheet with you and answer any questions you may have. You will be informed of which foods are currently being tested. At the end of the talk, you will be given as much time as you need to decide whether or not to take part, but this will be at least 24 hours. You will not be contacted during this time. If you decide to take part, you will need to contact a member of the study team to arrange an eligibility appointment. You will also be invited to complete a short online 'pre- screening questionnaire', which will help the study team to prepare for your next appointment.

► **Informed Consent and Eligibility** *(Virtual Appointment, 1 h)*

Before we complete the eligibility assessment you will be asked to sign a hard copy of a consent form agreeing to take part in one GlyCarb study. This part of the appointment will need to be audio and video recorded by the study team member. You will also be asked to sign a hard copy of a medical declaration form and a meal specification form which describes the ingredients in the food to be tested (specific to each GlyCarb study). You will need to post the hard copies of these forms to the study team using a pre-paid envelope provided so that they can be countersigned by a study team member. A copy of the signed forms will be posted back for you to keep. After signing the consent form, you are still free to withdraw from the study at any time without giving a reason.

A research nurse from the Quadram Institute Clinical Research Facility (QI CRF), which is an NHS facility managed by Norfolk and Norwich University Hospital (NNUH) staff, or a member of the study team will then complete a brief eligibility health questionnaire with you. This will include some questions about your health and details of any medications you may be taking. This information will be used by the study team to assess your suitability to take part in the study. For example, you may be excluded at this point if you have any medical conditions or allergies that will prevent you from taking part.

At-Home Sample Collection *(up to 1h)*

For the final part of the eligibility assessment, we will require a sample of your blood (approx. ten drops from your finger) for clinical tests. You may also be provided with a weighing scale and measuring tape to help you determine your height and weight, (which we will use to determine your BMI).
An 'at-home sampling kit' with full written instructions will be posted to you. You can request to speak with a member of the study team at any time should you have any questions about the procedure.

You will collect the blood sample using a lancet that you press down on your fingertip to collect drops of blood. You won't see the needle, but you may experience some temporary bruising and discomfort where the needle has pricked the finger. Up to four finger-pricks may be needed to collect enough blood (approx. ten drops of blood) for the test.
The blood sample will need to be packaged in the envelopes provided and posted the same day. This will be used to measure your average blood sugar levels (HbA1C). This test will check for anything outside of the standard reference range, which may affect your wellbeing or the study data if you participate. You will be excluded from this study if you have an HbA1C above 42 mmol/mol and/or if you have a BMI below 18 or above 30 kg/m^2.

If any of your clinical results are outside the standard reference ranges, we may recommend that you speak to your General Practitioner (GP) about the results. All results outside the reference ranges are checked by the QI CRF medical advisor. The medical advisor will decide whether we may include you in the study, offer you the opportunity of a second screening (re-screen) or exclude you from taking part in the study. Please remember these tests are performed to determine whether you are suitable for the study not to find out if you are healthy. You will be invited to take part in this study if you meet all the listed criteria for participation and the blood test from the eligibility assessment is satisfactory.

► The Study *(2 weeks)*

►Day 1: Baseline assessment and CGM application (1 h)

Once eligibility is confirmed, you will be asked to complete a baseline assessment and continuous glucose monitor (CGM) application virtual visit. During this visit, we will explain how to collect baseline measures and to apply and use the CGM device, you will receive all study equipment needed for this visit. The baseline assessment includes, using a smart scale to measure body composition (fat% and muscle%) and completing a Food Frequency Questionnaire about your dietary habits (FFQ). The FFQ will be completed online and you will receive full instructions on how to do this.
A study team member will schedule the next appointment and arrange the delivery of the test meals to you.

In this study, you will consume a total of four carbohydrate-rich test meals (two different types of meal eaten twice) on separate days over a 2-week period of continuous glucose monitoring. These four meals will all have a similar taste and appearance. The test meals have been chosen for scientific reasons and might not be what you would normally expect to eat for breakfast. You will be told more about the meals during the study talk and will receive a written description ('Meal Specification Sheet') which explains how the meals should be prepared, along with a photograph, a list of the ingredients and nutrition information, to help you decide whether or not you want to take part in the study.

The order in which you consume the meals will be randomly assigned by a computer programme.
Neither the research team nor you will know in which order you are consuming them.

►Day 2: Evening restrictions

You will be required to: avoid alcohol; avoid strenuous exercise (e.g., hiking, jogging at 6 mph or faster, basketball or a football game); avoid having a high calorie meal (more than 1000 kcal) in the evening; and to fast for 12 h before the test meal is consumed. For example, you should

not eat or drink anything other than water after 7 pm on day 2 if the test meal is to be consumed at 7 am on Day 3. You will be reminded to follow these restrictions and to scan the glucose monitor every 6 to 8 h. **It is important that you adhere to the instructions provided by the study team. Failure to do so may require your withdrawal from this study.**

► Day 3 – Test Meal Day

You will consume the test meal after a 12 h fast. A member of the study team will guide you through this process on the first test day.

You will first be required to complete an online form with a few questions about your health, hunger levels and description of the test meal. You will then scan the CGM device and take a photo of the test meal immediately before eating it at the pre- agreed time. Once you have eaten the test meal, you will answer a few more questions about your hunger levels and provide some feedback on the test meal.

For the next 4 h you should not have anything else to eat or drink other than water and avoid any exercise if possible. You will be prompted to rate your hunger/ fullness every hour up until you have your next meal. You will be wearing the glucose monitor, so we will use the data recorded by the device to find out how the test meal affected your blood sugar levels.

►Day 4, 6, 8

Same restrictions as Day 2.

►Day 5, 7, 9– Test Meal Days

Same procedure as Day 3, with a different test meal on each day. A member of the study team will always be ready to speak with you on the test days, and you may decide if you want to arrange a virtual appointment on each day, or if you are confident to follow the test day protocol on your own. You can decide how much support you want from the study team on the test days.

►Day 10 – Final Virtual Appointment

A member of the study team will contact you to thank you for your participation in the study and remind you to scan the sensor one last time, remove the sensor, and return the device with any other study equipment. You will also be invited to provide feedback on your experience of participating in the study through an online Participant Feedback Questionnaire.

What will happen to the samples I provide?

The blood sample you provide at the eligibility assessment will be analysed at the fully accredited (ISO 15189) partner laboratories of Medichecks®. The results will be sent to the study coordinator who will discuss them with the medical advisor to determine eligibility. The study coordinator will communicate these results to your GP.

Access to personal information

Once recruited onto the study you will be given a code number. This number will be unique to you and is used to protect your information and make your samples pseudo-anonymous (it will not be possible to identify you as individual). The information that can link them to you will be available only to the research team. Access to your personal information is restricted to the research team, CRF research nurses and medical advisor and your GP. Further details about this are given in Part 2 of this information sheet.

Expenses and payments

Participation in these studies is done on a voluntary basis. However, we do recognize that being involved in the study can cause you some inconvenience. You will receive an inconvenience payment of up to £62 for participation. If you are excluded from the study or you withdraw from the study, the inconvenience payment you receive will be pro-rata (adjusted according to how much of the study you completed before exclusion/withdrawal). The postage costs for study related materials and samples are covered by the study.

Please note that payments are liable to tax and you are personally liable for your own tax assessment. If you are claiming state benefit, your entitlement may be affected by payments made for participating in the study. Quadram Institute Bioscience employees will be taxed via the payroll.

What are the risks and side effects from taking part in this study?

There can be a small amount of discomfort associated with taking the blood sample at the eligibility assessment This may affect some people more than others. The areas may be slightly tender, sore or bruised after the procedure, but this should fade within a short period of time.
The continuous glucose monitoring device (sensor) placed on the back of the upper arm should not be more uncomfortable than the finger prick. The sensor is kept in place with an adhesive. You may experience some irritation when removing the sensor which should fade within a short space of time.

Some test meals may be high in fibre. If you are not used to fibre in your diet, it is possible that you may experience bloating or wind after eating some test meals.

What are the potential benefits of taking part?

There are no direct benefits to you as a result of taking part in this study. However, the information we collect from this study will help us to develop scientific evidence to underpin the design of new food products that are beneficial to our health.

Will my taking part be kept confidential?

Yes. We follow Ethics and Research Governance requirements. All information about you will be handled in confidence. More details about this are included in Part 2 of this information sheet.

This concludes Part 1 of the information sheet.

If the information in Part 1 has interested you and you are considering taking part, then it is important that you read the additional information in Part 2 before making any decision.

Part 2

What if relevant new information becomes available or changes to the study are made?

If this happens, we will let you know. If changes to the study are made and they impact on your participation, you will be given the new amended participant information sheet to read before being asked to sign another consent form.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time without giving a reason. However, the study scientist will need to be informed of your decision to withdraw. Any data collected until the point of withdrawal will be retained and used for this study. You will receive payment pro rata for samples given up to the point of withdrawal.

If you withdraw from the study, unless you state otherwise, any biological samples which have been collected whilst you have been in the study will be used for this research as detailed in this participant information sheet. However, you are free to request that your samples are destroyed at any time during the study.

In the event of loss of capacity during the study, any data and samples collected until this point will be retained and used for this study unless you request that your samples are destroyed at the time of consent.

What if there is a problem?

If you have a concern about any aspect of the study, you should ask to speak to a member of the study team who will do their best to answer your queries. You can telephone Dr Marina Corrado at 07920 545769 or leave a voicemail for the study team at 01603 255050 or email us at

GlyCarb@quadram.ac.uk.

If you remain unhappy and/or wish to complain formally, you can do this through the chairperson of the Quadram Institute Bioscience Human Research Governance Committee Dr Antonietta Hayhoe on (01603) 255030 or Antonietta.Hayhoe@quadram.ac.uk.

Quadram Institute Bioscience accepts responsibility for carrying out trials and as such will consider claims from participants for any harm suffered by them as a result of participating in the trial, with the exception of those claims arising out of negligence by the participant. Quadram Institute Bioscience has liability insurance in respect of research work involving human participants. Please note that the institute will not fund any legal costs arising from any action unless awarded by a court. Furthermore, NHS bodies are legally liable for the negligent acts and omissions of their employees.

If you wish to complain or have any concerns about the way you have been treated by Quadram Institute CRF staff whilst taking part in this study, there will be a local hospital complaints procedure that you can follow. If you wish to complain you should contact the Patient Advice and Liaison Service (PALS) on 01603 289036 (email: pals@nnuh.nhs.uk). Their offices are located next to Kimberley Ward, East Block Level 2 or please ask at the main reception desks at the Inpatient and Outpatient hospital entrances. The office has an answerphone which is available 24 hours a day and messages will be responded to as quickly as possible.

Will my taking part on this study be confidential?

Only personal and heath information that is needed for the study will be collected and this will be held in the strictest confidence. Access to your personal records is restricted to the study team, the Quadram Institute CRF nurses and medical advisor and your GP. All personal information is kept in locked cupboards at the Quadram Institute.

Once recruited onto the study you will be issued with a participant code

number.
This number will be used on all your personal information and samples so that nobody else will know or be able to work out that they are yours. Coded information is also kept in a locked filing cabinet at the Quadram Institute but separately to your personal information.

Your data will be stored in a secure archive for fifteen years after the end of the study. It will then be destroyed. Any archived identifiable data will not be used to contact you after the end of the study.

All research is subject to inspection and audit and although your records may be accessed for this purpose any personal information remains confidential.

We would like to share your views and comments about the study anonymously on social media, as a study testimonial. This is on a voluntary basis, saying 'No' will not prevent you from taking part.

Data protection

The Quadram Institute Bioscience (QIB) is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.
QIB will share identifiable data with NNUH team at the Quadram Institute CRF. Access to your personal records is restricted to the study team, the QI CRF research nurses and medical advisor, and your GP.
All information collected about you during this study will be kept strictly confidential. We follow Ethics and Research Governance and Good Clinical Practice (GCP) requirements. The study will comply with EU General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018. The legal bases used under the regulation that we employ to process your personal information is for tasks carried out in the public interest, which this study and associated research is.

Your rights to access, change or move your information are limited, as

we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible and work with trustworthy service providers (*LibreLink app* by Abbot and Medichecks®) to ensure your personal information is safe.

During the study, you will be asked to use certain external applications/services to record your medical information.
Accounts will be created for you, using the unique participant information number assigned to you and a unique, study- specific email address which cannot be linked to you. If you would like further information on how these third-party services handle/process your data, please refer to their privacy policies as follows:
Freestyle Libre Glucose monitoring system: privacy policy
Medichecks: privacy policy
The online FFQ is hosted on Typeform: privacy policy

Due to the nature of the service provided by Medichecks, we will need to share your gender and year of birth with them, but your name will not be shared. Any blood samples collected will be disposed of once the screening analyses are completed.

A courier service may be used to deliver foods and study equipment to your home. To use this service, your address will be shared with a trusted courier service for the purpose of this study only, which will keep your information confidential.

You can find out more about how we use your information by contacting the QIB Data Protection Adviser, dpa@nbi.ac.uk] or QIB study sponsor representative [Dr Antonietta Hayhoe Antonietta.Hayhoe@quadram.ac.uk].

Will my GP be informed?

Yes. It is routine practice to inform your GP that you are taking part in a study at QIB. We will also send your GP details of all your clinical screening results (blood tests, weight and BMI measurements). Your permission will

be sought, and this is one of the things you are agreeing to when you sign the consent form. If any of these blood results fall outside the standard reference range, we may recommend you speak to your GP about it. We are unable to discuss your blood results with you.

What will happen to the results of the research study?

As a participant you are valuable to us, but we are unable to tell you any of your individual results. The general findings of the study, however, will be given to you in the form of a letter.

Results may be published in scientific journals or presented at meetings. It is also possible that data arising from this study will be shared with other researchers to support future research. To this end, the study data collected may be shared anonymously with other third parties, including those in other countries (outside of the European Economic Area).
At the end of the study, we will try to provide feedback about what we have found as a result of your involvement in this study and what it may mean for future research. Please note that data are presented in anonymous form. Your name will not appear anywhere in any of the results presented, shared or published.

Who is funding the study?

This study is being funded by the Biotechnology and Biological Sciences Research Council (BBSRC UK).

Who has reviewed this study?

To protect your safety, rights, wellbeing and dignity, this study has been reviewed and approved by the QIB Human Research Governance Committee (HRGC) and an independent group of people called the National Research Ethics Committee Cambridge South.
The study is registered on Clinicaltrials.gov, a publicly-available database. It is good practice for all research projects to be registered in a publicly-accessible database and this supports our duties to promote research transparency.

What you need to tell us?

We do need you to tell us some things for your safety and for the success of the study. Some medication may affect the information we are collecting so you need to tell us if you take any medication. You will also need to tell us if you become pregnant whilst on the study. Should you become unwell during the study then you need to tell us.

What happens if I become unwell during the study?

If you become unwell during the study, we may ask you to stop participating in our research. This will, of course, depend on the nature of the illness and whether or not it will affect the study outcome. In a medical emergency, you should contact the emergency service (via 999) and please ensure that your GP and the study team are informed as soon as practicably possible.

What should I do now?

If you are interested in taking part in the study, then please send an email to GlyCarb@quadram.ac.uk

If you are not interested in taking part, you need not do anything. No one will contact you about the study.

The Chief investigator of the GlyCarb Remote study is
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(01603) 251466

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