Participant Information and Informed Consent for Participation in the Study

Influence of a multi-day soccer camp on glycaemic control in children and adolescents with type 1 diabetes mellitus.

A quasi-experimental observational study.

Dear participant,

Dear parent or legal guardian,

we warmly invite you to take part in the above-mentioned study. You will be informed about the contents of the study in a detailed consultation. Please note the following information first: **Your participation in this study is voluntary. You can withdraw from the study at any time without giving reasons. Refusal to participate or withdrawal from this study prematurely will have no negative consequences for you.**
This form of scientific study is necessary to obtain reliable and evidence-based research results. However, an essential prerequisite for conducting a study is that you and your parents or legal guardians give your written consent to participate in the study in advance. Therefore, please read the following text carefully as a complement to the informative consultation with the study team, and do not hesitate to ask questions if anything is unclear. Please only sign the informed consent if you

- have fully understood the nature and procedure of the study

- are willing to agree to participate,

- are aware of your rights as a participant in this study.

The responsible ethics committee of the University of Bayreuth has issued an approval for the study protocol as well as for the present participant information and informed consent (No.: 24-047, 27 September 2024).

1. What is the purpose of this study?

Physical activity and/or exercise is an integral part of modern diabetes therapy. Many studies have shown that patients who are more physically active have better glycaemic control and can significantly reduce the occurrence of diabetes-specific comorbidities. However, many people with type 1 diabetes (T1D) continue to refrain from regular physical activity, with exercise-induced hypoglycaemia being one of the main reasons. To ensure that exercise protocols are safe and effective for patients with T1D, further scientific data is needed. Therefore, the aim of this study is to investigate glycaemic control in children and adolescents before, during and after a multi-day soccer camp in children and adolescents with T1D.

2. How is the study conducted?

This study is a non-interventional, observational study that will take place as part of the K1ck Without Limits Football Cup from October 25 to October 27, 2024, in Neufahrn near Freising. Children and adolescents under the age of 18 with diagnosed T1D can participate. The type of insulin therapy (pen or pump) does not matter. However, wearing a CGM sensor is a prerequisite. Non-interventional observational study means that you participate in the soccer tournament as you usually would and without the study team having any influence on your blood glucose control. At the end of the study, the study team will only request an export file of your insulin and CGM data. In addition, you will keep a diary during the study period in which you ought to document your physical activity and therapy measures. For instance, in this diary you will record the time when you play soccer, when you use the sports mode or which target values you set and for how long. Your diary will be collected at the end of the soccer camp and sent to the study centre.

3. What is the personal benefit of the study?

You have no personal benefit from your study participation. However, you will make a valuable contribution to gaining knowledge in diabetes research and help people with type 1 diabetes worldwide to be able to exercise safely and efficiently.

4. Are there risks, complaints and side effects?

As this study is a non-interventional observational study, participation in the study is not associated with any risks.

5. Insurance

This study is not covered by insurance.

6. When will the study be terminated prematurely?

You can revoke your willingness to participate and withdraw from the study at any time without giving reasons. This will not result in any disadvantages for you. The study team will inform you immediately of any new findings that become known in relation to this study and that could be significant for you. On this basis, you can then reconsider your decision to continue participating in this study. However, it is also possible that the study team may decide to end your participation in the study prematurely without first obtaining your consent. The reasons for this may be:

- You do not meet the study requirements
- The study team has the impression that further participation in the study is not in your interest

7. Data privacy

Regarding the data collected and processed as part of this study, a fundamental distinction must be made between

- any personal data by which you can be directly identified (e.g. name, date of birth, address, photographs, etc.),
- pseudonymized (encrypted) personal data, in which all information that allows direct conclusions to be made as to your identity is replaced by a code (e.g. a number) or (e.g. in the case of image recordings) made unrecognizable. This means that the data can no longer be assigned to your person without additional information and without disproportionate effort, and
- anonymized data that can no longer be traced back to you personally.

The encryption code is kept strictly separate from the encrypted data records and is only kept at your study centre. Only the study team has access to your non-encrypted data. The data is protected against unauthorized access. In addition, authorized representatives of the university sponsor (Professor Dr. Othmar Moser) who are obliged to maintain confidentiality, as well as representatives of domestic and/or foreign health authorities and the relevant ethics committees,

may inspect the unencrypted data if this is necessary or required to verify the proper conduct of the study. The data will only be passed on in encrypted or anonymized form. Only the encrypted or anonymized data will also be used for any publications. You can withdraw your consent to the collection and processing of your data at any time. After your revocation, no further data will be collected. However, the data collected before you withdraw your consent may continue to be used in the context of this study. Due to the legal requirements, you also have the right to access your personal data and the possibility of rectification if you discover errors, unless this would make it impossible or seriously impair the implementation of the study.

The duration of the study is 3 days. The duration of the storage of your data beyond the end of the study is regulated by law. If you have any questions about the handling of your data in this study, please contact the study team or the sponsor's data protection officer:

Mr. Thomas Frahnert

ZUV (Room 1.17)

Universitätsstraße 30 in 95440 Bayreuth

Phone: +49 (0) 921 / 55 – 5335

Email: datenschutz@uni-bayreuth.de

8. Are there any costs for the participants? Is there a reimbursement of costs or remuneration?

Your participation in this study will not incur any additional costs for you. Also, there will be no compensation for expenses.

9. Emergency number (24 h availability)

In an emergency, please call an emergency hotline immediately (while in Germany: **112**).

10. Study Contact

If you have any questions about your participation in the study, please contact:

Mathias Walter

FC Diabetes e.V.

Munich, Germany

Email: diaball@fcdiabetes.de

Phone: +49 (0) 89 / 8890784

or

Dr. Janis Schierbauer

Div. Exercise Physiology & Metabolism

Bayreuth Centre of Sport Science (BaySpo)

University of Bayreuth

Email: janis.schierbauer@uni-bayreuth.de

Phone: +49 (0) 921 / 55 - 3475

Informed Consent

Name, Surname: _

Date of Birth: _ _ _ _ _ _ _ _ _ _

I have been informed in detail and comprehensibly by Mr./Mrs./Ms. _ _ _Mathias Walter_ _ _ about the entire study, strains and risks as well as about the nature, significance and scope of the study, the existing insurance and the resulting requirements for me and hereby declare my willingness to participate in the said study. Furthermore, I have read the text of this informative leaflet and informed consent carefully and in its entirety. Any questions that arose were answered clearly. I have had sufficient time to make my decision and currently have no further questions.

I will follow the instructions that are necessary for the execution of the study, but I reserve the right to terminate my voluntary participation at any time without any disadvantages for my further care.

I expressly agree that my data collected as part of this study may be used as described in the data protection section of this document.

If I withdraw from the study, I agree that my data files will continue to be stored and analysed.

☐ yes ☐ no

I am aware that I can request that my data be deleted at any time. Mrs. Anita Langsteiner (anita.langsteiner@uni-bayreuth.de, phone: +49 (0) 921 / 55 - 3465) is responsible for the data.

I have received a copy of this subject information and informed consent form. The original remains with the study team.

I hereby confirm that the information provided above is correct.

_____________________ Place, Date

__________________________ Signature Legal Guardian of Study Participant

__________________________ Signature Study Participant

The investigator confirms that he/she has provided all necessary information about the tests. From his/her point of view, the subject has understood the content and objectives of the tests as well as the possible risks resulting from participation.

Bayreuth, 27.10.2024
Place, Date

i.A.
Signature Investigator

The participant receives a signed copy of the participant information and informed consent; the original remains in the study team's study folder.