

COVER PAGE

Official study title: Addressing health disparities in childhood obesity, one summer at a time.

NCT number: NCT03595332

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Parental Permission

Title of Study: Addressing health disparities in childhood obesity, one summer at a time.

Principal Investigator: Hendrik 'Dirk' de Heer, PhD, MPH

Why is this study being done?

The study involves research. The study offers a summer program to children in the Flagstaff area. The study is being done because many children in Flagstaff at high risk for conditions like diabetes and obesity. Summer is the time when many children gain the most weight. Summer programs can help keep kids active in the summer, but many families cannot afford summer programs. We want to test out whether a summer program can make children more active. The summer program is based on a national campaign that includes collaboration with local organizations. Our program provides children with free access to facilities of local organizations and improve physical activity during the summer.

What will happen if my child takes part in this study?

If your child participates, this consent form is required to be signed. Also, the child is required to sign an 'assent' form, to show that they want to participate. After signing, both parent and child are asked to complete a survey. The survey asks about basic information, for example how old you are, and for parents what the household characteristics are. The survey also asks about activity habits, norms and barriers. We also ask that we can measure your child's height and weight and use your child's height and weight information already collected by the school district.

After the survey, each child will receive a 'Scorecard'. This scorecard will be given at the beginning of the summer and includes 24 activities to do in and around Flagstaff. Activities are either at local facilities such as the aquaplex, flagstaff athletic club, and cabin fever. The scorecard will give you free access to these places. When your child completes an activity at the local business, they receive a stamp. There are also some activities that can be done outside (like hike for 1hr) and for those, parents can sign off. At the end of the 10-week project period, children return their scorecards to us, and we ask your child to complete the same survey they did at the beginning.

Will there be any cost to my child to take part in this study?

There are no costs to participate in the study for your child.

What are the risks and/or discomforts my child might experience if you take part in this study?

The project includes physical activity in and around Flagstaff. Being physically active comes with a risk of soreness or injury. No funds have been set aside to compensate injuries occurring from activities. In addition, there is always a minor chance of loss of confidentiality of your child's information. We have taken steps to limit this risk.

Are there any benefits for your child if you choose to allow them take part in this research study?

Your child will receive a scorecard which allows them to access local facilities for free. The information we learn from this project can help support future summer programs. Since the summertime is so important for reducing risk for chronic disease such as diabetes, more free summer programs could be impactful in our community.

Will my child be paid to take part in this study?

Your child will not be paid for their participation in this research study. However, the summer scorecard provides free access to local facilities, and small prizes are provided at the beginning and the end of the program. The prizes at the end will be a bit bigger for children who did more activities.

Will my child's study-related information be kept confidential?

Efforts will be made to keep your child's study-related information confidential. For example, their name will not be used in any of our analyses. Instead we will use random ID numbers. Only the researchers have access to the surveys and other data. All reports from the project will be presented as summaries of all the children participating.

This study is funded by the federal government through the National Institutes of Minority Health and Health Disparities. Because the study receives federal funds, the information about the project and summary findings will be posted at the ClinicalTrials.gov website. This includes a description of the project and summary findings. This will not include personal identifying information or anything linking an individual to the study.

There may be some uncommon circumstances where study information must be released. For example, personal information regarding your child's participation in this study may be disclosed if required by state law.

Also, your child's records may be reviewed by the following groups:

- *Office for Human Research Protections or other federal, state, or international regulatory agencies*
- *Northern Arizona University Institutional Review Board*
- *The sponsor supporting the study, their agents or study monitors*

To help us protect your child's privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify your child except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency-funded projects or for information that must be disclosed in order to meet the requirements of the Federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your child's involvement in this research. If an insurer, medical care

provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Will my child's study-related information be used for future research?

Information collected about your child will not be used or shared for future research studies.

Who can you call if you have any questions?

If you have any questions about taking part in this study or if you feel your child may have suffered a research related injury, you can call the Principal Investigator at 928-523-1499 or dirk.deheer@nau.edu.

For questions about your child's rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Research Protection Program at 928-523-9551 or online at <http://nau.edu/Research/Compliance/Human-Research/Welcome/>.

If your child is injured as a result of participating in this study or for questions about a study-related injury, you may contact the principal investigator, the human subjects research protection program or your child's school principal.

An Institutional Review Board responsible for human subjects research at Northern Arizona University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

CONSENT:

I have read the above information and have been given an opportunity to ask questions. I give my consent for my child to participate in this research project, and I have been given a copy of this consent document.

Print Name of Child(ren)