

The “Great Live and Move Challenge” study to evaluate the impact of a program to promote physical activity among children aged 7-11 years.

Submission date 09/04/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/06/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/04/2019	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Recent surveys have reported that a large majority of children did not meet the physical activity (PA) international guidelines in France, Europe and in the US. Indeed, more than 80% of US adolescents, 66% of European adolescents, and in France, 69% of school-aged children did not meet the international guidelines. Therefore, there is a need to find efficient programs to improve PA habits in children from early age.

The Great Live and Move Challenge (GLMC) study evaluates a complex intervention to promote PA practice in children aged 7-11 years from French primary schools, by comparing an intervention group who receives the GLMC, and a control group who do not receive any intervention.

The Theory of Planned Behavior (TPB), a theory that explains the adoption of a behavior such as PA behavior, is the basis of the intervention. This study will evaluate the effectiveness of a complex intervention for PA promotion involving multiple levels of intervention (i.e., school teachers, municipal officials, and policy stakeholders) and based on a behavioral theory (i.e., the TPB) and potentially provide valuable information for schools and public health policers looking for innovative PA programs. It aims to show that the GLMC intervention will increase the proportion of children meeting the World Health Organization recommendations of 60 minutes /day of moderate to vigorous PA, by 15%.

Who can participate?

Children in school years 2 – 4 at Hérault, Gard, and Aude French departments

What does the study involve?

Communities of communes are randomly allocated to one of the two study groups. The GLMC program is implemented on children and their parents and involves multiple local partners, such as school teachers, municipal officials, and policy stakeholders. The program is followed for two years, for 3.5 months each year and all the included children are followed during 24 months. Children and parents are evaluated before and after the program every year regarding PA

practice (self-reported and data measured in a sample of 400 children), TPB variables (i.e., intentions, attitudes, personal norms, perceived behavioral control) and other psychosocial variables (e.g., perceptions of active opportunities).

What are the possible benefits and risks of participating?

Children and parents involved in the intervention group benefit from the GLMC PA promotion program that is expected to increase their PA practice. By promoting PA among children and their parents in association with the education community, one of the long-term indirect finality of the GLMC program is to prevent metabolic and chronic diseases (e.g., obesity, diabetes, cancer) in all of the family members who received the intervention. There are no particular risks for children and parents participating in the study. There are no invasive evaluations, and PA practice is proposed in safe settings and conditions.

Where is the study run from?

Schools recruited in Hérault, Gard, and Aude French departments (France)

When is the study starting and how long is it expected to run for?

September 2015 – June 2018

Who is funding the study?

1. Institut National Du Cancer (France)
2. SIRIC Montpellier Cancer (France)

Who is the main contact?

Prof Florence Cousson-Gélie (Public)

Florence.Cousson-Gelie@icm.unicancer.fr

Study website

<http://www.gdvb.fr/> and <http://www.icm.unicancer.fr/fr/prevention/le-grand-defi-vivez-bougez>

Contact information

Type(s)

Public

Contact name

Prof Florence Cousson-Gélie

ORCID ID

<http://orcid.org/0000-0002-8195-9170>

Contact details

Univ Paul Valéry Montpellier 3

Laboratoire Epsilon

Route de Mende

Cedex 05

Montpellier

France

34199

+334 67 61 3000

Florence.Cousson-Gelie@icm.unicancer.fr

Type(s)

Public

Contact name

Dr Mathieu Gourlan

Contact details

Epidaure Prevention Department of the Institut régional du Cancer de Montpellier (ICM)
208 Avenue des Apothicaires
Montpellier
France
34928

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CCTIRS no. 15279; CNIL no. 1860542

Study information

Scientific Title

The “Great Live and Move Challenge”: a program to promote physical activity among children aged 7-11 years. A cluster-randomized controlled trial.

Acronym

GLMC

Study objectives

Primary objectives:

1. Measure the effects of the multilevel TPB-based GLMC intervention on PA practice
2. Increase the proportion of children meeting the current international recommendations of 60 minutes of moderate to vigorous daily PA by 15% at 24-month follow-up.

Secondary objectives:

1. Increase children’s scores of intentions, attitudes, subjective norms, perceived behavioral control and planning toward PA as well as their level of perceptions of active opportunities
2. Increase among parents the level of PA social support toward their children and the level of involvement in shared family PA.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. French Advisory Committee on Information Processing in Material Research in the Field of Health (Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la Santé, CCTIRS), 15/06/2016, ref:15279
2. French Data Protection Authority (Comission Nationale de l'Informatique et des Libertés, CNIL), 14/04/2016, ref:1860542

Study design

Two-armed interventional prospective cluster-randomized controlled trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Healthy children

Interventions

Communities of communes are randomized with equal allocation to one of the two study arms:

- 1) the GLMC experimental arm receiving a 24-month (6 weeks each year) multilevel and TPB-based program aiming to promote PA practice;
- 2) the control arm that do not receive any intervention.

The cluster randomization of communities of communes is computer generated considering an approach by minimization and stratification, by an independent statistician (DRCI University Hospital of Clermont-Ferrand, France), using the Stata software (StataCorp, College Station, Texas, US). The randomization is stratified according to department and urban/rural condition to avoid unbalanced representation of communities of communes regarding these criteria. After randomization, schools belonging to the communities of communes and their teachers are informed about the study and arm allocation. Eligible children and their parents from schools and classes willing to participate in the study receive a written information note explaining the research goal, design, and requirements regarding assessments, especially accelerometer wear, and intervention content.

The intervention is implemented on children and their parents and involves multiple local grass-roots partners, such as school teachers and municipal officials, as well as policy stakeholders from town councils and community of communes. The total duration of the GLMC is three and a half months each year, for two years. It starts at the beginning of January and ends at mid-April each year, and comprises two major steps: (1) The first two months are devoted to the implementation of the GLMC with local partners; (2) The last month and a half is devoted to the intervention on parents and children within two phases: (2a) A 2-week "motivational" phase

aiming to increase intentions to practice PA; and (2b) A 1-month “volitional” phase aiming to facilitate the translation of increased intentions into an effective lifestyle adoption.

The GLMC consists of the use of behavior change techniques intended to children and their parents and in the implementation of “PA events” (i.e., PA sessions) both within schools and the community. Based on the CALO-RE taxonomy, the intervention for children consists of “providing information on consequences of behavior to the individual” and “prompt self-monitoring of behavior.”

In accordance with previous TPB-based interventions in the PA domain, children are first provided with information related to some of their most salient beliefs regarding PA. During a 20-minute session implemented within the first 2 weeks of the intervention in each class involved, a member of the research team presents to children the benefits of practicing PA in order to “have fun,” “stay fit,” and “improve skills.” The use of the self-monitoring technique among children has been adapted with a playful method to help them quantify their PA practice. Inspired by the “The Grand Défi Pierre Lavoie” (<https://www.legdpl.com>) implemented in selected schools of Quebec (Canada), children involved in the GLMC are proposed to cumulate and count “energy cubes.” More precisely, an “energy cube” is equivalent to 15 continuous minutes of PA. Children are invited to monitor their PA every day and report on a diary every time they cumulated one “energy cube” throughout the duration of the GLMC. Of note, teachers are asked to help children to monitor their “energy cubes” at least three times per week during the 4 weeks of the intervention.

With regard to the involvement of parents, the GLMC consists of “providing information on consequences of behavior to the individual.” During a 30-minute session, parents are invited to a meeting during which they are informed of the benefits of shared family PA (i.e., “to have fun,” “to strengthen the relations within the family,” and “to lower the risk of disease for all the family members”) and those of supporting their children toward PA (i.e., “helping him/her to find flourishing activities,” and “helping him/her to be more responsible of his/her health”). One session in each school is conducted within the first 2 weeks of the intervention for the parents of the children who take part in the GLMC.

The GLMC also consists of an implementation of PA events both within the school and the community (such a component is not referenced in the CALO-RE taxonomy). All children involved benefit from one “PA event” per week organized by the teachers of the school during the intervention, as well as PA events organized in collaboration with local policy stakeholders (e.g., town councils). The promotion of those “PA events” is made through advertisement in local papers, websites, and posters in streets and schools.

Intervention Type

Behavioural

Primary outcome measure

Physical activity practice in hours per week in children is self-recorded using an adapted version of the self-administered Physical Activity Questionnaire for Children (PAQ-C)

All measurements are assessed at four time points i.e., pre- and post-intervention each year for two years as follows:

- year 1, at pre-intervention 1 (T0), baseline
- year 1, at post-intervention 1 (T1), end of intervention 1, 4.5 months after baseline
- year 2, at pre-intervention 2 (T2), 12 months after baseline, 7.5 months follow-up after the end of intervention 1
- year 2, at post-intervention 2 (T3), end of intervention 2, 16.5 months after baseline.

Secondary outcome measures

In children:

1. Physical activity is measured using an Actigraph GT3X+ accelerometer in a subsample of 400 children at ...
2. TPB variables (i.e., attitudes, subjective norms, perceived behavioral control and intentions) are measured using a questionnaire developed based on existing guidelines and previous TPB research among children.
3. Planning is measured using a questionnaire including five items based on the French version of the action planning scale.
4. Perceptions of active opportunities are assessed using a questionnaire including five items based on previous studies (e.g., Bélanger-Gravel et al. 2010).

In parents:

1. Shared family physical activity is assessed using a questionnaire developed by Rhodes et al. (2010)
2. Physical activity parents' social support to their child is measured using a 3-item self-administered questionnaire inspired by the "praise and understanding" subscale of the Parental Involvement In Sports Questionnaire.

All measurements are assessed at four time points i.e., pre- and post-intervention each year for two years as follows:

- year 1, at pre-intervention 1 (T0), baseline
- year 1, at post-intervention 1 (T1), end of intervention 1, 4.5 months after baseline
- year 2, at pre-intervention 2 (T2), 12 months after baseline, 7.5 months follow-up after the end of intervention 1
- year 2, at post-intervention 2 (T3), end of intervention 2, 16.5 months after baseline.

Overall study start date

01/09/2015

Completion date

31/12/2018

Eligibility

Key inclusion criteria

1. Attend primary school (year 2 to year 4)
2. From Hérault, Gard, and Aude French departments

Participant type(s)

Healthy volunteer

Age group

Child

Sex

Both

Target number of participants

4000

Key exclusion criteria

None

Date of first enrolment

05/01/2016

Date of final enrolment

31/01/2017

Locations

Countries of recruitment

France

Study participating centre

Schools recruited in Hérault, Gard, and Aude French departments

Montpellier

France

-

Sponsor information

Organisation

French National Cancer Institute (Institut National du Cancer)

Sponsor details

52 Avenue Morizet

Boulogne-Billancourt

France

92513

+33 (0)1 41 10 50 00

contact@institutcancer.fr

Sponsor type

Government

Website

<http://www.e-cancer.fr/>

ROR

<https://ror.org/03m8vkq32>

Funder(s)

Funder type

Government

Funder Name

Institut National Du Cancer

Alternative Name(s)

The French National Cancer Institute, INCa

Funding Body Type

Private sector organisation

Funding Body Subtype

Research institutes and centers

Location

France

Funder Name

SIRIC Montpellier Cancer

Results and Publications

Publication and dissemination plan

Planned publication in high-impact peer reviewed journals; the protocol by 2018 and the trial results by the end of 2019.

Intention to publish date

31/12/2019

Individual participant data (IPD) sharing plan

The data will be held at Epidaure, Institut du Cancer de Montpellier, France. Epidaure is the principal investigator of the study and then is responsible for the dataset. Individuals who consent to participate in the study did not give their agreement for their data to be used by other investigators.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/04/2019		Yes	No