

The Swiss Preschool Health Study (SPLASHY)

Submission date 21/03/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/05/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/11/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The aim of the study is to investigate how stress and/or physical activity influences children's psychological and physiological health at preschool level by focusing on four aspects: cognitive functioning, psychological well-being, adiposity (obesity) and motor skills.

Who can participate?

1150 children aged 2 to 6 of both genders

What does the study involve?

The child is tested at the start of the study and a year later. There are a number of tests, interviews and questionnaires.

What are the possible benefits and risks of participating?

The benefits of the study are three afternoons of different activities for the child. Previous research has shown that children enjoy the tests. There are no known negative side effects. The children get a little stuffed animal (called Splashy) and a T-shirt. Parents get a financial incentive for their efforts related to the study.

Where is the study run from?

The study has been set up by four research centers in three universities in Switzerland (Lausanne, Fribourg, Zurich).

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

February 2014 to December 2016

Who is funding the study?

1. The Swiss National Science Foundation (Switzerland)
2. The Jacobs Foundation (Germany)

Who is the main contact?

Prof. Jardena Puder
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Study website

<http://splashy.ch/>

Contact information

Type(s)

Scientific

Contact name

Prof Jarden Puder

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Relationship of stress and physical activity with psychological and physiological health in young children

Acronym

SPLASHY

Study objectives

The primary aim of the study is to investigate how stress and/or physical activity influences children's psychological and physiological health at preschool level by focusing on four aspects: cognitive functioning, psychological well being, adiposity and motor skills. It is assumed that:

1. Exposure to environmental stressors (major life events, chronic day-to day stressors), chronic physiological stress responses such as dysregulations of the hypothalamic-pituitary-adrenal (HPA) axis and the autonomic nervous system (ANS), and the acute stress reactivity (i.e., individual susceptibility) to a standardized stressor correlate with/predict increased adiposity,

reduced cognitive functioning and reduced psychological health (i.e., including mood, behavioral problems and dysfunctional eating behavior scores).

2. High levels of total and moderate-to-vigorous physical activity correlate with/predict low adiposity, higher cognitive functioning and higher levels of motor skills and to fewer behavior problems and eating disorders.

The strength of association may vary with age. In addition, the moderating role of psychological children's (lifestyle, temperament, emotional well-being and self regulation) and environmental characteristics (family atmosphere, parental style, socioeconomic status, childcare center characteristics and large sociocultural environment such as German-French speaking parts of Switzerland) may influence the relationship of stress and physical activity on psychological and physiological health outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cantonal Ethics Committee, Canton de Vaud, Switzerland, 19/09/2013 (initial acceptance), 14/01/2014 (amendment), ref: 338/2013

Study design

Multi-center prospective cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Patient information can be found at: <http://splashy.ch/> or <http://splashy.ch/fr/>

Health condition(s) or problem(s) studied

Children, preschool

Interventions

If parents consent to participation in the study, their child is tested at two time periods including a baseline assessment and a follow-up (1 year later). A longer follow-up is planned. Baseline assessment includes three afternoons of tests of the children in the childcare setting including motor skills, medical, cognitive and adaptation tests and assessment of self regulation. During the 3 weeks of testing, children are asked to wear an ECG monitor during 24 hours (to measure heart rate variability, a measure of the ANS) and an accelerometer (to measure physical activity) during 1 week. Parents are asked to fill out two questionnaires (general health and lifestyle and psychological questionnaire including temperament, eating behavior, well-being, mood and parenting skills), participate in a telephone interview and to collect saliva for measures of

cortisol (HPA) and alpha-amylase (measure of the ANS) of the child over 2 days, and to collect fingernails (HPA). Childcare educators are asked to fill out a questionnaire.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The relationship of stress exposure, perception, behavior and physiological stress responses (using salivary cortisol and alpha-amylase daily profiles, cortisol in nails and heart rate variability) and physical activity (using an accelerometer) at baseline and at 1 year follow-up on children's health outcome at baseline and at 1-year follow-up including:

1. Psychological health, defined as
 - 1.1. Mood (Strength and Difficulties questionnaire sdq [Goodman, 1997])
 - 1.2. Behavioral problems (Strength and Difficulties questionnaire sdq [Goodman, 1997])
 - 1.3. Eating behavior (Children's Eating Behaviour Questionnaire CEBQ [Wardle et al., 2001])
2. Physiological health, defined as
 - 2.1. Cognitive functioning (Intelligence and Development Scales - Preschool IDS-P [Grob et al., 2009])
 - 2.2. Physical activity (accelerometry)
 - 2.3. Adiposity (BMI, waist circumference, skinfolds)
 - 2.4. Motor skills by using the Zurich Neuromotor Assessment ZNA3-5 (Largo, Calfisch & Jenni, 2007)

Secondary outcome measures

1. Investigation of moderating factors, whenever applicable, including:
 - 1.1. Psychological child factors at baseline and at 1-year follow-up: social behavior (Strength and Difficulties Questionnaire SDQ [Goodman, 1997]) and temperament (Emotionalitäts-Aktivitäts-Soziabilitäts-Temperamentinventar [Buss, A. & Plormin, R., 1994]); self-regulation capacity by using the statue test NEPSY ([Olsen et al. 1998] and/or delay of gratification [DOG], behavioral factors including lifestyle behavior [i.e. sleep and media use])
 - 1.2. Environmental factors at baseline and at 1-year follow-up such as:
 - 1.2.1. Family setting including socioeconomic status (SES, including migrant status, educational level and income), parenting style (Alabama Parenting Questionnaire APQ [Reichle & Franiek, 2009], parental stress (Parental Stress Scale [Berry, 1995]) and family atmosphere (Parental expressed emotions Five Minute Speech Sample FMSS; Magana, 1986; Leeb et al., 1991) and health attitudes of the parents
 - 1.2.2. Childcare setting including childcare quality and health promotion
 - 1.2.3. Sociocultural environment
 - 1.3. Physiological health at baseline and at 1-year follow-up (physical activity by using accelerometer), adiposity (BMI, waist circumference and skinfold) and health problems (i.e. disease, symptoms)
2. Investigation of vulnerable time periods for effects of major life events or chronic stressors at baseline and at 1-year follow-up

Overall study start date

01/02/2014

Completion date

31/12/2016

Eligibility

Key inclusion criteria

Current inclusion criteria as of May 2014 (trial record updated 16/03/2016):

2-6 year-old children of governmental and private childcare centers are randomly selected by stratifying socioeconomic status (SES) level. Each childcare center provides 12 children at maximum.

Previous inclusion criteria:

3-5 year-old children of governmental and private childcare centers are randomly selected by stratifying socioeconomic status (SES) level. Each childcare center provides 12 children at maximum.

Participant type(s)

Patient

Age group

Child

Lower age limit

2 Years

Upper age limit

6 Years

Sex

Both

Target number of participants

500 (1150 children contacted within n=96 child care centers)

Total final enrolment

463

Key exclusion criteria

Unable to do the tests

Date of first enrolment

01/03/2014

Date of final enrolment

01/12/2015

Locations

Countries of recruitment

Switzerland

Study participating centre

University of Lausanne

Lausanne

Switzerland

1010

Study participating centre

University of Fribourg

Fribourg

Switzerland

1700

Study participating centre

University of Zurich

Zurich

Switzerland

8001

Study participating centre

Children's Hospital Zurich – Eleonore Foundation

Zurich

Switzerland

8032

Sponsor information

Organisation

Swiss National Research Foundation (Switzerland)

Sponsor details

Wildhainweg 3

Postfach 8232

Bern

Switzerland

3012

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sinergia@snf.ch

Sponsor type

Research organisation

ROR

<https://ror.org/00yjd3n13>

Funder(s)**Funder type**

Research organisation

Funder Name

Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)

Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Switzerland

Funder Name

Jacobs Foundation

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Switzerland

Results and Publications

Publication and dissemination plan

Future publications in high-impact peer-reviewed journals are planned 2017 -2019

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository [TEAMDRIVE 3]

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/07/2016		Yes	No
Results article	results	04/04/2018		Yes	No
Results article	results	31/10/2019	04/11/2019	Yes	No
Results article	secondary outcomes on parenting styles	22/11/2022	25/11/2022	Yes	No