

# PRoF Award abstract – Call 2018

Deadline for submission: Thursday March 1<sup>st</sup> 2018 (12 o'clock noon)

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## 'WELCOME TRIAL'

### 1. Research Outline

Acronym	WELCOME
Project name in English	Improving WEight controlL and CO-Morbidities in children with obesity via Executive function training.
Pitch (1 sentence)	The aim of this project is to improve weight control and comorbidities in obese children and adolescents through executive function training on top of a multidisciplinary obesity treatment program.
Executive summary (max. 10 lines)	Multidisciplinary obesity treatment (MOT) programs are effective in the short term. Weight regain after treatment is however common and significant. Lack of behavior control capacities could explain this adverse development. The present project studies the outcomes of a combined MOT program + executive function training that strengthens behavioral control capacities in a specific patient group, being obese youth. The WELCOME trial is a multicenter longitudinal, prospective randomized controlled trial from 1 January 2017 until 1 January 2020. Effects of the EF-training will be visible by enhanced executive functioning (compared to control training) but, more importantly by its effect on different health markers: 1) better weight loss maintenance up to 6-months follow-up, 2) reduced medical comorbidities such as metabolic syndrome, obstructive sleep apnea and cardiovascular function, 3) enhanced well-being.

## 2. Cause and context of the research

**Rationale:** Childhood obesity represents an enormous health burden and its prevalence is still increasing. One in five (20%) Belgian children (aged 2-17) are overweight; 7% of them are obese<sup>1</sup>. The rationale for treating children with obesity is underlined by overwhelming research on its several associated medical and psychosocial comorbidities, such as obstructive sleep apnea (OSA), cardiovascular diseases (e.g., atherosclerosis, endothelial dysfunction), type II diabetes mellitus, depression, and decreased self-esteem<sup>2-6</sup>. It is estimated that every year obesity related comorbidities take 8% of all medical health costs<sup>7</sup>. Further, more than half of the obese school-age children will grow up to become obese adults<sup>8,9</sup>, showing that childhood obesity is not a transient developmental phenomenon, but a chronic problem. Finally, a high BMI during childhood has been associated with increased risk of coronary heart disease and premature death from disease at adult age<sup>10,11</sup>. Tackling weight problems in childhood is therefore important for both children's and adult's health and for society. However, existing weight loss treatments have only limited success, specifically at long-term. The scientific community has an important responsibility in research on maintaining post-treatment weight, which will have impact on the physical and psychological well-being and will reduce the long-term risks of morbidity and mortality.

One of the explanations for the modest and pessimistic results of existing therapies is that obese children and adolescents have decreased behavioral self-control capacities compared to normal weight peers: they lack the skills of resisting temptation<sup>12-16</sup>. Basic research demonstrated that this can be explained by poor executive functions (EFs) needed to overrule automatic behaviors. EFs are neurologically based processes (e.g., attention, inhibition) needed for self-control and resisting temptation. They are implicated in eating behaviors, with strong EFs associated with a healthier diet and lower weight. In children with poor EFs, overweight is more prevalent than in those with strong EFs. It is also shown that EFs have an influence on obesity treatment, with impulsive individuals having more difficulties losing weight<sup>17-19</sup>, maintaining weight loss<sup>20</sup> and leaving the treatment more often<sup>21</sup>. The UGhent group started in 2011, as the first group worldwide, to investigate the potential of an EF-training for obese youth. The study proved that a computerized EF-training on top of a multidisciplinary obesity treatment (MOT) enhances EFs of obese youth, and increases their capability to maintain weight loss until 8 weeks follow-up (FU), thereby providing a proof-of-concept for the present project<sup>12</sup>.

**Aim:** The aim of this project is to show that an evidence-based MOT focusing on behavioral lifestyle benefits from adding this novel EF- training. More specifically, we aim at strengthening the evidence for MOT + EF-training in realizing (a) better weight maintenance until 6-month FU and (b) health benefits by an improvement in medical and psychological health comorbidities. Utilization will be shown in three different settings and for different age groups.

**Method:** We aim to set up a multicenter longitudinal, prospective RCT within 'Het Zeepreventorium', De Haan (inpatient treatment), Jan Palfijn Ziekenhuis, Ghent (secondary outpatient treatment) and Antwerp University Hospital (tertiary outpatient treatment). During the regular treatment in these settings, 200 obese children (8-18 years) will be randomized on a 1/1 base to either a 6 week computerized EF-training (12 sessions; n=100) or an active control condition (12 control sessions; n=100), followed by 8 weekly booster sessions (8 extra EF-training sessions or 8 extra control sessions). The effects of the EF-training will be measured after the training, at 2 months and 6 months FU. Effects of the EF-training will be visible by enhanced executive functioning (compared to control training) but, more importantly by its effect on different health markers: 1) better weight loss maintenance up to 6-months FU, 2) reduced medical comorbidities such as inflammation, metabolic syndrome, cardiovascular function and obstructive sleep apnea (OSA), 3) enhanced well-being.

The obtained budget would be used to further optimize the EF-training based on results and feedback from this project and for other costs associated with the current RCT.

**Dissemination:** During the project, we see utilization as the broad-scale dissemination of the computerized EF-training in multidisciplinary obesity treatment centers. The computerized training will be presented to all multidisciplinary obesity treatment centers (ca 25-30 in Flanders; reaching approximately 3000 overweight and obese children/year) in collaboration with different partners from an advisory board (BASO, VVK and Eetexpert.be vzw) representing the majority of health professionals who are dedicated to the treatment of childhood obesity. The multidisciplinary obesity centers will be able to implement the training without additional costs for them. A manual and one-day train-the-trainer program will be developed for therapists supervising the training. The project results will be disseminated to different target groups. First, by showing utilization for different settings and for different age groups on health outcomes, we can convince all professionals in Flanders to use the EF-training on top of MOT. Results of the project could also be of interest for other target groups specifically when self-control is indicated for health related behavior, such as diabetic children. The project team members will publicize and report on the activities and results of the project on a broad basis, including press releases and provision of information to appropriate stakeholders such as parents, health authorities, medical societies and organizations working on health in children and adolescents. Results will also be communicated at national and international meetings. Furthermore, because of the close collaboration of the project leaders with the Universities of Ghent and Antwerp, future psychologists and physicians will be educated about the project results.

### 3. Innovation results achieved

1. The present project will tackle a serious health problem in children: the obesity problem. Although a MOT program aiming at lifestyle changes and ensuring parental involvement

when treating children, is still seen as efficient, effective and cost-effective **the innovative challenge for obesity research is analyzing the problem of the maintenance of weight control after participating in a MOT.**

2. Based on recent evidence and own results<sup>12,15,22-26</sup>, we hypothesize that the failure of self-regulation plays a major role in long term weight control specifically in an obesogenic overwhelming food environment for children that have strong automatic bottom-up processes as well as deficits in reflective top-down control processes, due to poor executive functions (EFs). So, as long as obese children do not strengthen their EFs, the skills acquired in treatment remain of limited capacity. Therefore, **programs tackling EFs on top of MOT can be seen as innovative and highly indicated** for both weight control and, even more importantly, related health outcomes.
3. **Innovation here is based on objective data.** Rigorous experiments have provided behavioral and neuroscientific evidence for the EF deficits in obese and, even more important for their plasticity via interventions targeting these processes in response to food by training inhibition or attention. Several independent studies suggest that training individuals to inhibit responses to high-calorie foods via computerized tasks resulted in weight loss<sup>27-30</sup>. Moreover 2 recent meta-analyses concluded that EFs can be trained and have both near and far transfer effects in the domain of food and drinks, also in younger age groups<sup>31,32</sup>. This extends our proof of concept study in obese children with an inhibition training (which was world-wide the first) showing the effects for obese children participating in an attention modification program<sup>12</sup>.
4. Based on the proof-of-concept studies, with this project we can convince professionals in Flanders **that innovation is now highly indicated/feasible in all MOT settings treating children and adolescents with obesity** (3000/year) for establishing significantly better weight loss maintenance and health benefits on both psychological and medical comorbidities, by strengthening EFs.
5. **The innovation goal is thereby imbedded in research on optimal clinical practice**, whereby the EF-training (here specified with tasks both on attention and inhibition) have to be practiced for six weeks during treatment (12 sessions) and continued in aftercare during eight weeks and taking into account sufficient practice and motivational elements. Feasibility analyses will be conducted and will show if clinical practice must tailor the program to child characteristics.
6. After the project, we guarantee broad-scale **dissemination of our innovation research findings** by promoting the computerized EF-training imbedded in optimal clinical practice which will enhance the quality of the obesity treatment programs in Flanders.
7. However, of even greater **innovation is raising public and scientific awareness** on the role of neuropsychological processes for behavioral self-control which will also further increase the understanding of the obesity problem.

## 4. Link to the PRoF values

### *Awareness*

*Awareness implies that sick, disabled or elderly people should have a good feeling about the concept or solution offered by PRoF. When people feel better, they recover faster and feel happier in their environment.*

During this project, we have already gained important insights on the training's feasibility and noticed that awareness and motivation are crucial to how participants respond to the program. As a result, substantial effort is made to support participants in increasing their motivation and their self-efficacy feelings. More specifically, when participants are aware of the usefulness of the EF-training (how it can help them) and can translate this main purpose into personal goals, they feel more motivated about the extra training. Preliminary data on feasibility confirms this assumption, and shows that the motivational and self-efficacy ratings are high when participants start the training process. When patients feel that they can benefit from the intervention and are capable to change their self-control behavior, they experience less barriers and are more motivated to put in the extra effort.

### *Comfort*

*Comfort describes the minimal level of comfort that patients or elderly people need. This level varies among people as different persons have another estimation of what minimal comfort means*

Comfort is one of the main advantages of e-health interventions for several reasons. The web-based formula allows participants to train whenever and wherever they want. Equipped with only a computer and internet connection, they can decide for themselves when to train. They experience the comfort of working on their personal goals in their own environment, fitted within their own schedule. Moreover, they do not need extra support of care providers, which encourages their feelings of independency without feeling isolated from the treatment system.

### *Safety*

*It is important to bring a feeling of safety to patients and elderly people as they are in a vulnerable situation when in hospitals and other care situations.*

Obese children are a vulnerable population and it is important that they feel safe and supported during their treatment, which is also an important component for their motivation during the training. Participants are free to decide independently in every step of the program, and they will not be judged in any way on (not) following the program. They are always supported in this decision making process by their parents (or legal guardians) and by the facilities' care providers. Next, specific steps were taken to guarantee safety in the domain of online environment and data security. There was invested in a safe data collection protocol

together with a specialized company. All data is coded and only the treating physician or head researcher have access to the non-coded information.

### *Privacy*

*Privacy is used to indicate that personal privacy and cocooning are critical. Creating a homely feeling in hospitals and other healthcare institutions is key in PRoF.*

As we work with an e-health intervention, the patients are able to carry out the training in the comfort and privacy of their own home, or in an environment of their choosing. All data collected during this project will be coded and only the study coordinators will have access to the coding table. Each EF-training is password protected per patient (the patients chooses his own password at the beginning of the treatment and this only known to him), and only the treating physician can follow the progress of the patient in this process.

### *Loneliness*

*Recognizing that elderly persons are increasingly lonely in modern societies, guided PRoF to design solutions to avoid the feeling of “loneliness”.*

Social acceptance and the feeling of belonging to a group is important in the life of children, especially if they suffer from a chronic condition as obesity. Participants are supported and supervised during the MOT and EF-training by their trusted health-care professionals as well as the study team. Emphasis is made on the fact that they are not alone and others face the same challenges. Especially in the inpatient treatment setting, patients are surrounded by their peers on a daily basis and can find comfort in each other.

### *Non-stigmatizing*

*Technically a product can be perfect but people may be ashamed or humiliated when they have to use it; wheelchairs and walking racks were cases in point.*

By improving self-control processes conceptualized as focus and stop “power”, we prioritize the enhancement of the skills children already possess. We don’t target problematic behavior, but we empower the strengths of the child. If they feel in control of themselves and are more able to resist daily temptations, social situations in which eating is involved (for example going out with friends to see a movie) can become easier and consequently decrease stigmatization.

### *Intergenerational*

*For the PRoF 2.0 brainwave, 90% of the consortium members said they personally would want inter-generational solutions as they grew older; almost nobody wanted to live together only with other elderly people.*

Focusing on improving cognitive abilities enhances present self-control, but also sets the stage for later developmental phases. This project challenges to target those specific processes that are important in every stage of life. Furthermore by tackling the obesity problem at an early

age and by focusing on strategies for maintaining a healthy weight, these children have better chance to grow up to be healthy adults as it is known that many obesity-related comorbidities track from childhood to adolescence and adulthood.

### *Flexibility*

*Hospitals, healthcare facilities, and elderly houses should use the space in a flexible way.*

*Stays in hospitals become shorter (most surgeries take only one day stays), and chronically ill patients are cared for in specialized care facilities.*

Since an e-health formula is used, we don't put extra pressure on the care system itself. It does not request extra effort within the treatment facility, and can be implemented even in the aftercare phase without extra effort of care providers.

## **5. Applicable IPR rules**

Ghent University will provide free access to the online training, accessible on a server. The software needed for the computerized tasks requires 2 components: (1) a license, and (2) a code developed at Flinders University, including the instruction screens and the food pictures.

(1) First, the license for the software needed for both the attention task and the inhibition task (and control training) are well-known in university research projects and will be offered (free) by the Ghent university during the project and by Eetexpert.be vzw after the training (web-based).

(2) Second, Flinders University is happy to share the code that they have written on the provision (as per Flinders University's IP guidelines) that prof. Eva Kemps is a named collaborator and co-author on any publications, and any published/research material acknowledges that the software was developed at Flinders University. For the broad scale application they have no additional requests.

Since the beginning of 2015, the UGhent group set up an intense collaboration with Prof. Eva Kemps from Flinders University (see studies on EF and eating) who developed specific software for the EF-tasks with food-cue items. This collaboration between both universities is topic of a formal contract, drawn by our institutions Technology Transfer Department. Use of the software is guaranteed during but also after the project period, ensuring that the tasks can be used both during the project duration and for the utilization trajectory. Importantly, for use in treatment programs, they need to be imbedded in optimal clinical conditions.

The research consortium (UGhent, UZA and UA) made an initial agreement on further developing the MOT + EF-program and its dissemination within an optimal condition format, granting sublicenses only to multidisciplinary obesity treatment centers for non-commercial use in therapy after agreeing on the optimal clinical conditions. This will be coordinated by one of the partners in the advisory board (Eetexpert.be vzw, without commercial interest) and will take the format of a contract. So, Eetexpert.be vzw will supervise the non-commercial use in

therapy and the contract requirements, stipulated by the project leaders. The multidisciplinary obesity treatment centers can rely on Eetexpert.be vzw for the implementation of the training, materials, workshops and services.

An important article in the contract the multidisciplinary obesity treatment centers will stipulate that the promoters of the research groups are granted access to and free use of the (anonymous) EF-data for further research and continuous optimizing of the training.

## **6. Information on the partners**

### **WELCOME team**

#### **Ghent University**

##### **Faculty of Developmental Psychopathology**

Department of Developmental, Personality and Social Psychology  
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Prof. dr. Caroline Braet, Head of department  
Dr. Leentje Vervoort, postdoctoral researcher  
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#### **University Hospital Antwerp**

##### **Department of Pediatrics**

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Prof. dr. Stijn Verhulst, Head of department  
Prof. dr. Kim Van Hoorenbeeck, senior staff paediatrician, postdoctoral researcher  
Dr. Luc Bruyndonckx, pediatric fellow, postdoctoral researcher

#### **University of Antwerp**

##### **Laboratory of Experimental Medicine and Pediatrics (LEMP)**

Faculty of Medicine  
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Prof. dr. Benedicte De Winter, Director LEMP  
Dr. Annelies Van Eyck, postdoctoral researcher  
Dr. Marijke Ysebaert, PhD student, pediatric resident

*UGHENT, Clinical Developmental Psychology*

Prof. Caroline Braet supervises the research group “Clinical Developmental Psychology”, studying psychological mechanisms of psychopathology, eating and weight problems in children. She is author or co-author of over 130 scientific publications. The group is nationally and internationally recognized as an expert group, and prof. Braet is a well-known expert in behavioral change and effective treatment programs for obese children.

The group has several projects related to this project. For example, the group evaluated the first EF-training ever world-wide in obese children (PhD of S. Verbeken). Their REWARD project focusses on bottom-up processes, but also investigates the role of EF in eating behaviors. Next, the project builds on an extensive national and international network. Prof. S. Vanderoord (UVA Amsterdam/KULeuven), who studies EF-programs in ADHD, was involved in the first EF-study and evaluates the PhD process of Tiffany Naets in her guidance committee. The group has close contact with Prof. R. Wiers’ team (UVA Amsterdam), studying EF-training for different problems and involved in the second EF-study. Since 2015, there is intense collaboration with Prof. E. Kemps (Flinders University) who studies EF and eating and who developed the software for the EF-tasks with food items. PhD student Tiffany Naets will visit this research group later in 2018 to further elaborate the research network and to gain additional insights necessary for the optimal use of the projects’ data. However, researchers all over the world contacted the group to exchange insights, for example on a conference in 2014 (the Netherlands) and 2015 (USA and Sweden). The group is also involved in professional networks, e.g., Belgian Association for the Study of Obesity (BASO) and the European Child Obesity Group (ECOG). Together, they published position papers with treatment guidelines.

*Antwerp University Hospital, department of Pediatrics*

Prof. dr. Stijn Verhulst PhD-thesis was entitled “Sleep-disordered breathing in obese children and adolescents”. The first part studied the prevalence of OSA in obese children and the association with body fat. Second, it was demonstrated that OSA was an independent risk factor of the metabolic syndrome. In a third part, several mechanisms linking OSA with the metabolic syndrome, including inflammation, were investigated. In a final part, the effects of weight loss on OSA were studied. Several research lines originated from this PhD. One PhD thesis (Dr. K. Van Horenbeeck, 2013) looked at the effects of weight loss and residual OSA on parameters of the metabolic syndrome, oxidative stress, inflammation and adipokines. A second PhD thesis (Dr. A. Van Eyck, 2016) studied the role of the adipocyte in OSA in a pediatric obese population. Currently, Prof. Verhulst is head of the Department of Pediatrics at the Antwerp University Hospital. He is also a FWO Senior Clinical Investigator and currently supervisor of 4 ongoing PhD’s (including M. Ysebaert the PhD student on this project). Concerning international collaboration, he was the primary researcher for the hospital for a large multi-centers trial on the outcome of adenotonsillectomy for OSA in children. Screening for early cardiovascular damage in obesity and the pathophysiologic mechanisms are an important research topic within the Pediatrics department. This has resulted in several papers published in international peer-reviewed journals, and resulted in an additional PhD thesis (Dr. L. Bruyndonckx). In 2008, prof. Verhulst created together with 2 colleagues a European

collaboration of pediatric sleep centres. The aim of this collaboration is to work together on a clinical, educational and research basis. This collaboration has led to a consensus statement on pediatric OSA.

*University of Antwerp, Laboratory of Experimental Medicine and Pediatrics*

Prof. dr. Benedicte De Winter is director of the Laboratory of Experimental Medicine and Pediatrics (LEMP), a multidisciplinary research team incorporating fundamental, clinical and translational research activities of 7 laboratories of the Faculty of Medicine and Health Sciences (UAntwerp) and their clinical counterparts at the University Hospital. Prof. De Winter supervised 13 successfully defended PhDs and 6 ongoing PhDs. An external review board visited the faculty of Medicine and Health Sciences at the UA in 2014 and nominated LEMP as a very promising group with high impact and relevant research. The UA acknowledged the expertise of LEMP via the foundation of a center of excellence named 'Infla-Med'.

There is a strong collaboration within LEMP for the study of young patients with metabolic disease and obesity, studying the link between OSA, the metabolic syndrome and adipose tissue. They have a very valuable collaboration with 'Het Zeepreventorium'. In this population they also study the effect of diet and exercise training on microvascular endothelial dysfunction (PhD Luc Bruyndonckx, 2014). In this project, they found that obese children demonstrated microvascular endothelial dysfunction, the first sign of atherosclerosis. Next, they demonstrated that a 10 month residential treatment program is able to significantly improve microvascular endothelial function in obese children.

Note:

If your project is selected as laureate for the Award Symposium, a powerpoint presentation that reflects the project as suggested will be required (in advance), including a future plan how the funding will be used.

If your project is selected as the winner of the Award, you will be invited to present the results achieved thanks to the award during the Award Symposium of the next year.



## **Addendum: Contact information**

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