

**PLEASE NOTE:** *This trial has been registered retrospectively.*

## Trial Description

### Title

**Psychological and physiological consequences of exposure to mass media in young women - the role of moderators**

### Trial Acronym

**TSF**

### URL of the trial

<http://www.unifr.ch/psycho/de/research/klipsy/research>

### Brief Summary in Lay Language

**Mass media promoting unrealistic beauty ideals contribute to the normative discontentment with the own body of a large population of especially young women. In this research project we focus on the influence of daily exposition to beauty ideals in magazines on healthy women and women suffering from different psychological conditions: mixed mental disorder such as anxiety, somatoform and depressive disorders or eating disorders. The experimental group will be exposed to a fashion magazine, the control group to a nature magazine and the reaction of the two groups will be compared.**

**Therefore we assess the influence of media exposition on body image, mood and eating behavior as well as on the consequent bodily stress response. A negative body image does not only play a major role in the development of eating disorders but also seems to be crucial in the etiology of anxiety and depressive disorders. The project will thus shed light on the role of cognitive distortions such as "thought shape fusion, TSF" where the pure thinking of food and ideal bodies is assumed to be equal to weight gain and food intake. Additionally, components of the individual emotion regulation capacity are in the center of interest. We expect the findings to specify and differentiate existing models of development of a negative body image and the related risk for the development of further mental disorders, especially eating disorders. The results will foster early identification and prevention of especially eating behavior. Specifying the knowledge about the role of cognitive factors and emotion regulation with respect to the susceptibility to beauty ideals promoted via mass media will help to target and improve intervention strategies in eating disorders and beyond.**

### Brief Summary in Scientific Language

**In today's modern electronical world repeated exposure to thin beauty ideals is part of the daily routine. Data indicate that under certain circumstances, exposure to thin ideals via mass media plays an important role in the development and maintenance of eating disorders (EDs), low self-esteem and depressive feelings in young females. There are also contradicting results, revealing short-term positive effects of exposure to thin ideals. It is thus important to elucidate the specific circumstances under which exposure to thin ideals develops its detrimental**

**impact and to investigate whether these features are more pronounced in EDs than in other mental disorders also related to negative body image. However, despite the striking clinical relevance of detrimental effects of body dissatisfaction, negative affect and disordered eating behavior, the influence of moderators on effects of exposure to the thin ideal in ED samples compared to patients suffering from mixed mental disorders such as depression, somatoform disorders and anxiety disorders as well as to healthy controls has not yet been examined. Consequently, the current study sets out to investigate the following key questions:**

**(1) Does laboratory induced exposure to thin ideals relate to psychological impairments in terms of body image, affect and eating behavior in 18 to 35 year old female suffering from anorexia and bulimia nervosa (AN, BN) compared to female healthy controls and to a sample of females suffering from mixed mental disorders (depression, somatoform and anxiety disorders)?**

**(2) How do moderators such as cognitive distortions (“Thought-Shape Fusion, TSF”), and correlates of emotion regulation (ER) moderate the influence of the exposure to thin ideals?**

**(3) Are these characteristics amenable to change after treatment?**

**As a second focus it will be explored how exposure to media promoting the thin ideal relates to biological parameter of stress. We combine questionnaire-based and observational data and include biological measures of stress response such as saliva cortisol, alpha-amylase, heart rate and heart rate variability to assess impact of exposure to the thin ideal.**

**To achieve these interdisciplinary goals, two research groups (Prof. Dr. Simone Munsch, University of Fribourg, Switzerland; Prof. Dr. Silvia Schneider, Ruhr-University Bochum, Germany) provide their expertise for the investigation of ED pathology, negative affect, cognitive style, emotion regulation and psychological aspects of stress. As a specialist in terms of the concept TSF, Jennifer Coelho (Simon Fraser University, Vancouver) is participating as an expert in this study. Developmental aspects of body image and risk behavior in youth are covered by Grégoire Zimmermann (University of Lausanne, Switzerland), expertise on mechanisms transporting thin ideals promoted by mass media is guaranteed by W. Wirth, (University of Zurich) and expertise on computerized procedures for ER assessment is represented by Roberto Caldara (University of Fribourg, Switzerland).**

**A sample of 250 female participants including patients with AN, BN, depressive, somatoform and anxiety disorders, and healthy women will be recruited in four collaborating Clinics in Switzerland and in the University Clinic in Bochum. This project will provide pertinent findings about the role of moderators influencing the psychological and physiological effects of exposure to thin ideals promoted by mass media in AN and BN patients using an ecologically valid design. Comparing this susceptibility in ED patients to healthy participants and patients suffering from other mental disorder in a cross and longitudinal design will contribute to a better understanding of psychopathological mechanisms maintaining EDs and distinctions from depressive and somatoform disorders. Findings could be used to develop tailored interventions including a training in ER competences as well as cognitive restructuring of distorted beliefs about the own body shape and weight.**

**Do you plan to share individual participant data with other researchers?**

[---]\*

**Description IPD sharing plan**

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00005709**
- Date of Registration in DRKS: **2014/02/06**
- Date of Registration in Partner Registry or other Primary Registry: **[---]\***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **023/12-CER-FR , Kantonale Ethikkommission des Kantons Fribourg, Schweiz**

**Zudem wurde die Studie von den kantonalen Ethikkommissionen der Kantone Aargau, Thurgau und Zürich beurteilt, ebenfalls mit positivem Votum. Es gab keine Leit-Ethikkommission.**

## Secondary IDs

- Universal Trial Number (UTN): **U1111-1153-0040**

## Health condition or Problem studied

- ICD10: **F50.0 - Anorexia nervosa**
- ICD10: **F50.2 - Bulimia nervosa**
- ICD10: **F33 - Recurrent depressive disorder**
- ICD10: **F32 - Depressive episode**
- ICD10: **F40 - Phobic anxiety disorders**
- ICD10: **F41 - Other anxiety disorders**
- ICD10: **F45 - Somatoform disorders**

## Interventions/Observational Groups

- Arm 1: **Arm 1 - experimental group**

**Exposure material: magazine representing the female thin ideal (Vogue) in the waiting room.**

**The study will be conducted with four groups of participants:**

- 1) patients with Anorexia Nervosa**
- 2) patients with Bulimia Nervosa**
- 3) mixed clinical group (patients with depressive, somatoform and anxiety disorders)**
- 4) healthy control subjects**

**The participants in each group are randomly assigned to either the experimental or the control group. The data collection will proceed the same**

**way in all four study groups:****Pre-assessment, time point T1:****Week 1) Structured diagnostic interview (DIPS)****Week 2) Online questionnaires (BDI-II, BAI, BDDQ, RSES, DEBQ, EDE-Q, SATAQ-G, TSF trait, BIS-15, DERS, ASI-R, TPP, PACS)****Week 3) waiting-room experiment with a media exposure (magazine), imagination task (TSF induction), self-report questionnaires, (ThreeAS, FRS, VAS\_body image, VAS\_eating, Emoreg state, TSF state, TPP, PACS), assessment of heart rate and of saliva cortisol and saliva alpha-amylase at 9 time points, as well as an emotion recognition experiment (Expression Noise Experiment). 24h after the experiment: Post Event Processing Questionnaire, PEPQ.****Post-assessment, time point T2 (three months after the pre-assessment):****Week 1) Structured diagnostic interview (DIPS)****Week 2) Online questionnaires (BDI-II, BAI, BDDQ, RSES, DEBQ, EDE-Q, SATAQ-G, TSF trait, BIS-15, DERS, ASI-R, TPP, PACS)****Week 3) waiting-room experiment with a media exposure (magazine), imagination task (TSF induction), self-report questionnaires, (ThreeAS, FRS, VAS\_body image, VAS\_eating, Emoreg state, TSF state, TPP, PACS), assessment of heart rate and of saliva cortisol and saliva alpha-amylase at 9 time Points, as well as an emotion recognition experiment (Expression Noise Experiment). 24h after the experiment: Post Event Processing Questionnaire, PEPQ.**■ **Arm 2: Arm 2 - control group****Exposure material: neutral magazine (national geographic) in the waiting room****Characteristics**

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]\***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]\***
- Who is blinded: **patient/subject**
- Control: **Control group receives no treatment**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

**Primary Outcome****Outcome:****Body image: FRS, VAS\_Body****Mood: ThreeAS****Eating behavior: VAS\_Eating****Moderators: cognitive distortions (TSF) emotion regulation (ER)****Time points: T1 (pre), T2 (3 month after pre)****H1.1 We expect that exposure to thin ideal in contrast to neutral magazines**

**causes an impairment of body image (FRS, VAS\_body), affect (threeAS), and eating behavior (VAS\_eating).**

**H1.2 We expect that exposure to thin ideal in contrast to neutral magazines is related to more pronounced negative body image (FRS, VAS\_body), negative affect (threeAS), and disordered eating behavior (VAS\_eating) in individuals with AN (Anorexia Nervosa), BN (Bulimia Nervosa), and the clinical control group (depression, somatoform and anxiety disorders) compared to the healthy control group, both at T1 and less at T2.**

**H1.3 We expect that exposure to thin ideal in contrast to neutral magazines is related to more pronounced negative body image (FRS, visual VAS\_body), negative affect (threeAS), and disordered eating behavior (VAS\_eating) in individuals with AN and BN compared to the clinical control group, both at T1 and less at T2.**

**H1.4 We expect that the impact of thin ideal exposure on negative body image (FRS, VAS\_body), negative affect (threeAS), and disordered eating behavior (VAS\_eating) is moderated by cognitive style (TSFstate/ TSFtrait) and ER capacity. We expect stronger responses for participants with high TSF and low ER capacity.**

## Secondary Outcome

### **Outcome:**

**Stress response: salivary cortisol and alpha-amylase; heart rate and heart rate variability**

**Moderators: cognitive distortions (TSF) and emotion regulation**

**H2.1 We expect that exposure to thin ideal in contrast to neutral magazines causes a physiological stress response (increase in mean salivary cortisol and alpha-amylase concentrations, heart rate and decrease in heart rate variability).**

**H2.2 We expect that exposure to thin ideal in contrast to neutral magazines is related to a more pronounced stress response (increase in mean salivary cortisol and alpha-amylase concentrations, heart rate and decrease in heart rate variability) in clinical groups compared to the healthy control group, both at T1 and T2.**

**H2.3 We expect that the impact of thin ideal exposure is related to a more pronounced stress response (increase in mean salivary cortisol and alpha-amylase concentrations, heart rate and decrease in heart rate variability) in individuals with AN and BN compared to the clinical control group, at T1 and T2.**

**H2.4 We expect that the impact of thin ideal exposure on stress response (mean salivary cortisol and alpha-amylase concentrations, heart rate and heart rate variability) is moderated by cognitive style (TSFstate/ TSFtrait) and ER capacity.**

## Countries of recruitment

- CH Switzerland
- DE Germany

## Locations of Recruitment



- other **Lehrstuhl für Klinische Psychologie und Psychotherapie, Universität Fribourg, Schweiz**
- University Medical Center **Ruhr-Universität Bochum, Bochum**
- Medical Center **Kompetenzzentrum für Essstörungen und Adipositas, Spital Zofingen, Zofingen, Schweiz**
- Medical Center **Klinik Schützen, Rheinfelden, Rheinfelden, Schweiz**
- Medical Center **Privatklinik Aadorf, Aadorf, Schweiz**
- University Medical Center **Klinik für Psychiatrie und Psychotherapie, Zürich, Schweiz**
- Medical Center **LWL Klinik, Dortmund**
- Doctor's Practice **Bochum**
- Medical Center **Christoph Dornier Klinik, Münster**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/01/01**
- Target Sample Size: **250**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

## Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **35 Years**

## Additional Inclusion Criteria

**Inclusion criteria for the AN and BN group are based on DSM-5 assessed in face to face diagnostic interview (DIPS) and will be ascertained by the EDE-Q.**

**For the mixed mental disorder group, depressive, somatoform and anxiety disorders will be evaluated using the DIPS and will be ascertained by BDI-II, SOMS and BAI.**

**Inclusion criteria for the healthy control group are absence of past or present mental disorder according to the DIPS. For both, the healthy and the mixed mental disorders group the absence of EDs and the absence of a subclinical level of disordered eating behavior (EDE-Q general score below 2.5) is required.**

**Further inclusion criteria that apply to all groups are of 18 to 35 years of age, female gender, availability for and capability of study participation; informed consent, sufficient German language skills.**



## Exclusion criteria

**Exclusion criteria are pregnancy, psychotic disorders, and serious medical conditions having an effect on eating and mood. Individuals are all asked to report whether they receive medical prescriptions.**

## Addresses

### ■ Primary Sponsor

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## **Sources of Monetary or Material Support**

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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## **Status**

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2017/08/10**





## Trial Publications, Results and other documents

- Abstract <style fontName='DejaVu Sans' isBold='true'>Lennertz, J., Wyssen, A., Schuck, K., Schneider, S. & Munsch, S. Prädiktoren der kognitiven Verzerrung "Thought-Shape-Fusion (TSF)" bei Essstörungen. Beitrag am 9. Workshopkongress für Klinische Psychologie und Psychotherapie der Fachgruppe Klinische Psychologie und Psychotherapie der DGPs in Dresden, Deutschland (Mai 2015).</style>
- Trial results <style fontName='DejaVu Sans' isBold='true'>Wyssen, A., Coelho, J. S., Wilhelm, P., Zimmermann, G. & Munsch, S. Thought-shape fusion in young healthy females appears after vivid imagination of thin ideals promoted by fashion magazines; Journal of Experimental Psychiatry, 52, 75-82.</style>
- Paper **Publikation Studiendesign**
- Paper <style fontName='DejaVu Sans' isBold='true'>Wyssen, A. & Munsch, S. (2015). Wer ist die Schlankste im ganzen Land? Zeitschrift Universitas, 4, 38-39.</style>
- Paper <style fontName='DejaVu Sans' isBold='true'>Schuck, K., Munsch, S. & Schneider, S. Cognitive biases in response to visual body-related stimuli in eating disorders: Study protocol for a systematic review and meta-analysis. Published in Systematic Reviews, 2015, 4, 103. (<http://www.systematicreviewsjournal.com/content/4/1/103>)</style>
- Paper **Wyssen, A. (2015). State of the art and new perspectives in the diagnosis, prevention and treatment of eating disorders: a contribution to an etiological model of eating disorders - sociocultural risk factors and the role of body-related cognitive distortions. <http://doc.rero.ch/record/257986?ln=fr>**
- Trial results <style fontName='DejaVu Sans' isBold='true'>Wyssen, A., Rodger, H., Meyer, A.H., Humbel, N., Biedert, E., Caldara, R., Schneider, S. & Munsch, S. (31.08.-03.09.2016). Emotion recognition in female patients with eating disorders compared to females with mixed mental disorders and healthy controls. Vortrag anlässlich des 46. EABCT-Kongresses zum Thema „roots and present branches of CBT“ in Stockholm, Schweden.</style>
- Trial results **Lennertz, J., Schuck, K., Humbel, N., Wyssen, A., Biedert, E., Schneider, Silvia, Munsch, S. et al. (in prep.). Effects of thin-ideal exposure in media and mental imagery on self-reported outcomes in women with eating disorders compared to healthy and psychiatric controls. Manuscript in preparation.**
- Trial results <style fontName='DejaVu Sans' isBold='true'>Humbel, N., Messerli, N., Biedert, E. Schneider, S., Schuck, K., Lennertz, J. & Munsch, S. (September 2016). Influence of emotion regulation on stress responses in eating disordered patients. European Congress of Cognitive Behavioral Therapy (EABCT), Stockholm.</style>
- Trial results **Study protocol: psychological and physiological consequences of exposure to mass media in young women - an experimental cross-sectional and longitudinal study and the role of moderators**
- Trial results <style fontName='DejaVu Sans' isBold='true'>Wyssen, A., Debbeler, L.-J., Meyer, A.H., Coelho, J.S., Humbel, N., Schuck, K., Lennertz, J., Messerli-Bürgy, N., Biedert, E., Trier, S., Isenschmid, B., Milos, G., Whinyates, K., Schneider, S. & Munsch, S. (2017). Cognitive Distortions Associated with imagination of the Thin Ideal: Validation of the Thought-Shape Fusion Body Questionnaire (TSF-B). Frontiers in Psychology. </style>
- Trial results <style fontName='DejaVu Sans' isBold='true'>Wyssen, A., Coelho, J.S., Wilhelm, P., Zimmermann, G. & Munsch, S. (2016). Thought-shape fusion in young healthy females appears after vivid imagination of thin ideals. Journal of Behavior Therapy and Experimental Psychiatry, 52, 75-82 (doi: 10.1016/j.jbtep.2016.03.010)</style>
- Trial results **Munsch, S. (2014). Study protocol: psychological and physiological consequences of exposure to mass media in young women - an experimental cross-sectional and longitudinal study and the role of moderators. BMC Psychology, 37(2), (doi: 10.1186/s40359-014-0037-0)**
- Trial results <style fontName='DejaVu Sans' isBold='true'>Wyssen, A., Junpeng, L., Rodger, H., Meyer, A.H., Humbel, N., Schuck, K., Lennertz, J., Messerli-Bürgy, N., Trier, S.,

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Isenschmid, B., Milos, G., Flury, H., Schneider, S., Caldara, R. & Munsch, S. (resubmitted). Intact Facial Emotion Recognition Abilities in Seriously Mentally Ill Women. Psychosomatic Medicine</style>

- Trial results **Nadine Humbel, Nadine Messerli-Bürgy, Kathrin Schuck, Andrea Wyssen, David Garcia-Burgos, Esther Biedert, Julia Lennertz, Andrea H. Meyer, Katherina Whinyates, Bettina Isenschmid, Gabriella Milos, Stephan Trier, Dirk Adolph, Jan Cwik, Jürgen Margraf, Hans-Jörg Assion, Tobias Teismann, Bianca Ueberberg, Georg Juckel, Judith Müller, Benedikt Klauke, Silvia Schneider, Simone Munsch. (resubmitted). Emotion regulation difficulties have an impact on self-reported mood but not on biological stress response to thin ideal exposure. PLOS ONE**

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\* This entry means the parameter is not applicable or has not been set.

\*\*\* This entry means that data is not displayed due to insufficient data privacy clearing.