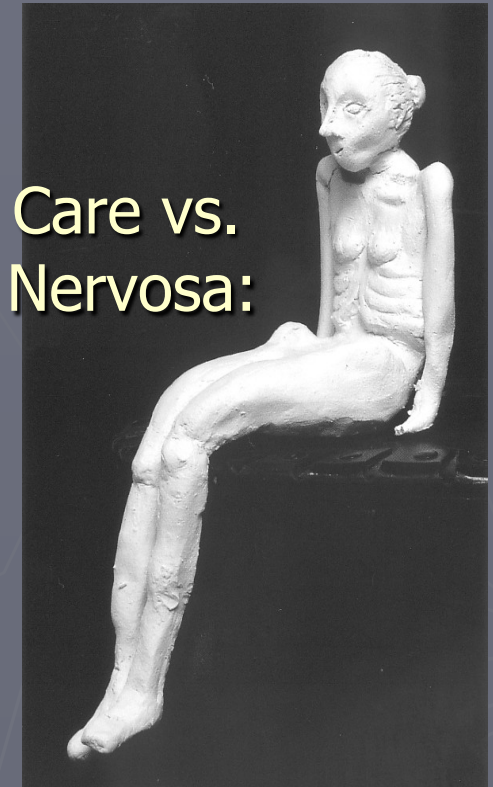# Day Patient Treatment after Short Inpatient Care vs. Inpatient Treatment in Adolescent Anorexia Nervosa:

results of a multicenter, randomized open-label, non-inferiority trial

ESCAP Dublin, July 2013

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Objectives I

1. With the exception of family therapy there is a dearth of studies on the treatment of adolescent AN;

2. In spite of insufficient research evidence inpatient setting (IP) is considered the treatment of choice especially for moderately to severely undernourished patients (APA 2006, German guidelines 2011);

3. High readmission rates have challenged this opinion (Gowers et al. 2007; Steinhausen et al. 2008)

4. Very few open studies on day patient treatment (DP) with small sample sizes exist, only one in adolescent AN. (e.g. Zipfel et al. 2002; Olmsted 2007, Goldstein et al. 2011)

Objectives II
Possible advantages of day patient in comparison to inpatient treatment

1. New skills might be better transferred to everyday life;

2. Maintaining contact to family and peers;

3. Better resumption of own responsibility;

4. Financial benefit.

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Inclusion criteria for randomized trial
– comparison of inpatient and day patient setting -

➤ AN according to DSM-IV criteria

➤ Body weight below 10th percentile

➤ First admission for AN

➤ Age: 11-18 years

➤ Female sex

➤ IQ > 85

➤ Distance fom residence to hospital within a 60 minute commute

Trial Sites in Germany – Localisation and settings

Precondition for participation:

Day patient *and* inpatient
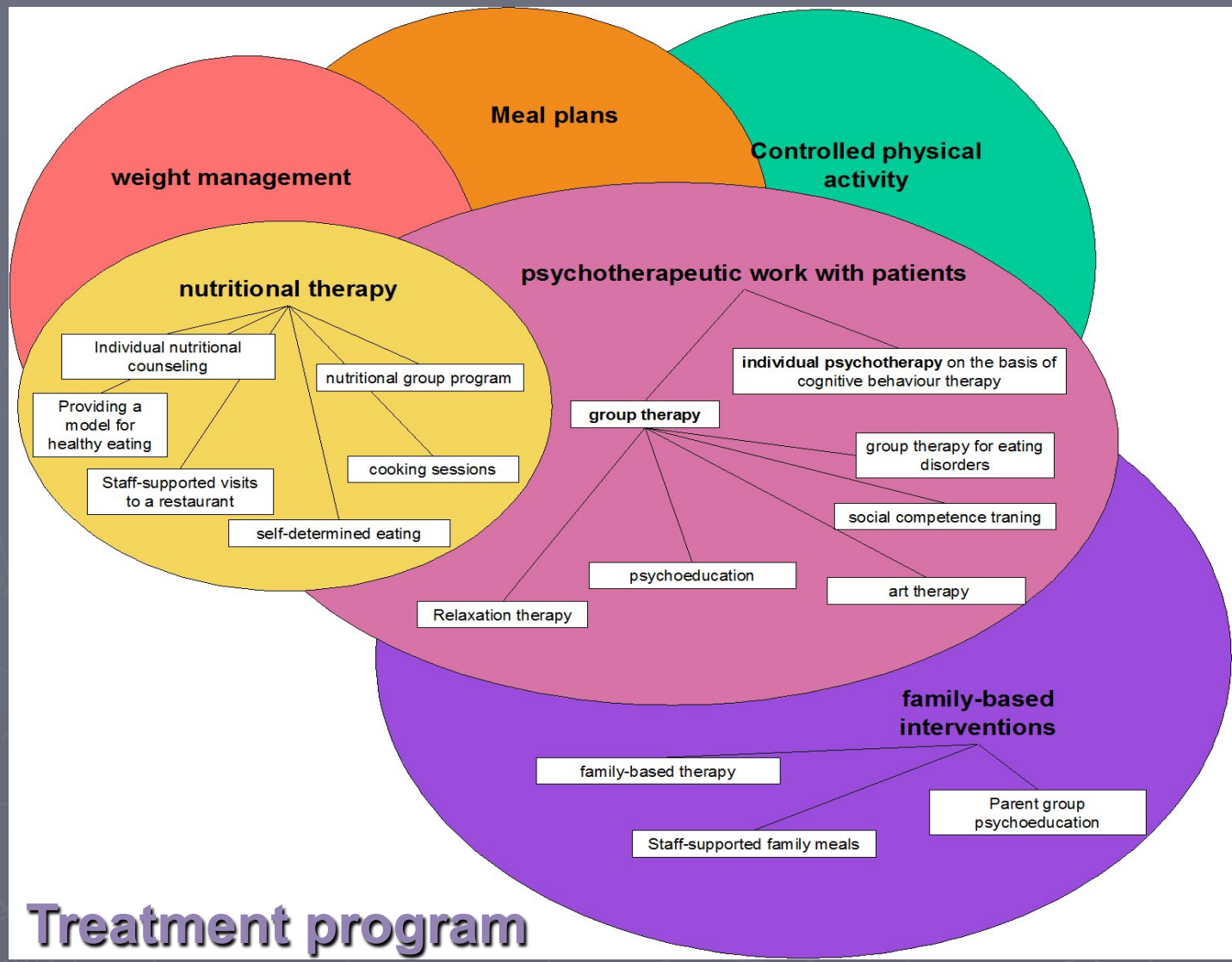
treatment setting at the

same department

6 Sites

Berlin

Aachen Köln
Düren

Würzburg

Freiburg

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RWTH AACHEN

Procedure:

1. Inpatient somatic stabilization period of three weeks

2. Randomization

3. Standardized identical multimodal treatment program in both settings till reaching target weight (15th -20th BMI percentile)

4. DP for 5 days a week (with few exceptions)

5. Followed by an outpatient individual and group therapy till 52nd week after admission

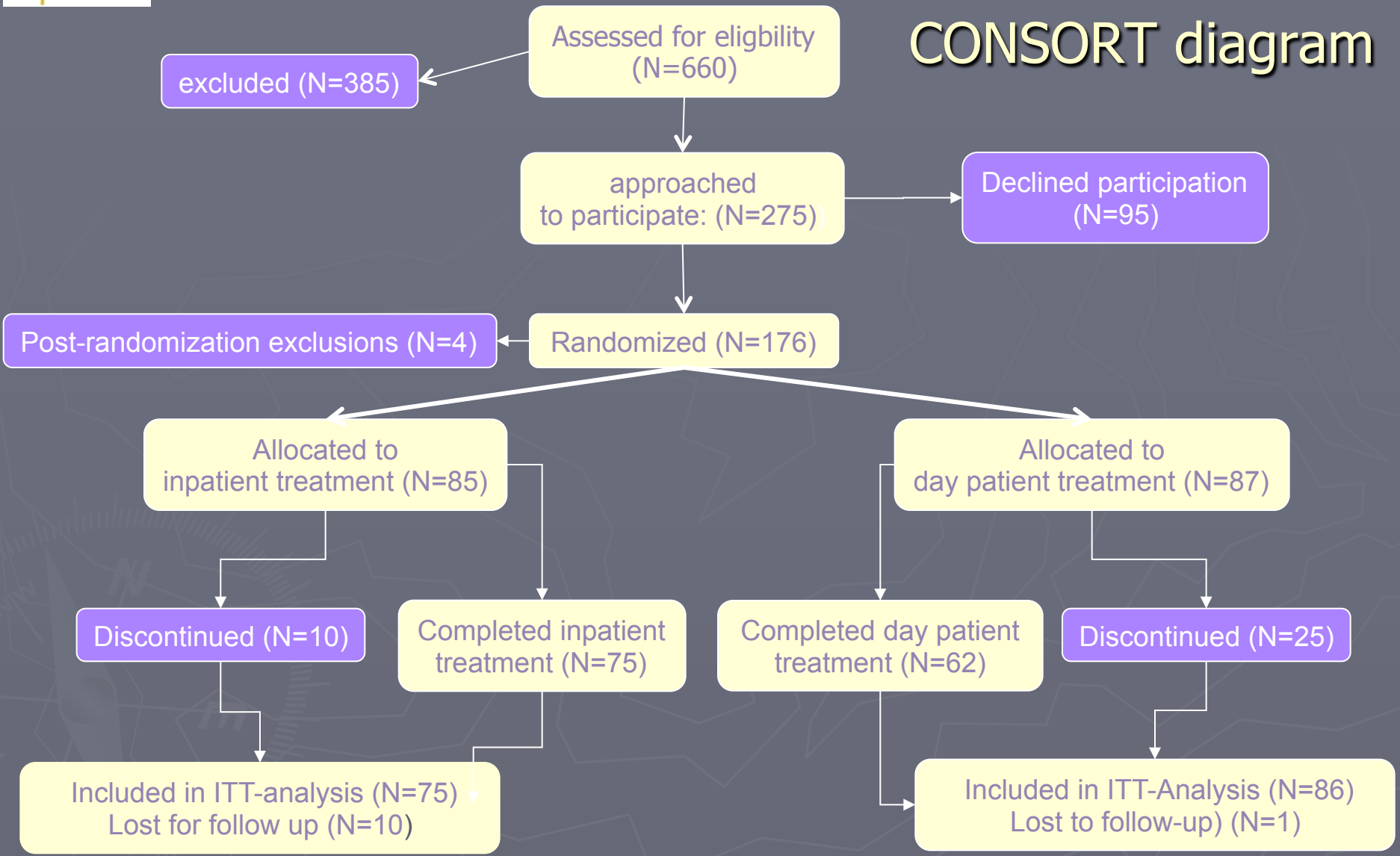**Hypothesis: DP is not inferior to IP**

Treatment program

- weight management
- Meal plans
- Controlled physical activity
- nutritional therapy
  - Individual nutritional counseling
  - Providing a model for healthy eating
  - Staff-supported visits to a restaurant
  - nutritional group program
  - cooking sessions
  - self-determined eating
- psychotherapeutic work with patients
  - group therapy
  - individual psychotherapy on the basis of cognitive behaviour therapy
  - group therapy for eating disorders
  - social competence traning
  - art therapy
  - psychoeducation
  - Relaxation therapy
- family-based interventions
  - family-based therapy
  - Staff-supported family meals
  - Parent group psychoeducation

Day patient treatment
– arriving in the morning by taxi -

CONSORT diagram

Assessed for eligbility
(N=660)

excluded (N=385)

approached
to participate: (N=275)

Declined participation
(N=95)

Randomized (N=176)

Post-randomization exclusions (N=4)

Allocated to
inpatient treatment (N=85)

Allocated to
day patient treatment (N=87)

Discontinued (N=10)

Completed inpatient
treatment (N=75)

Completed day patient
treatment (N=62)

Discontinued (N=25)

Included in ITT-analysis (N=75)
Lost for follow up (N=10)

Included in ITT-Analysis (N=86)
Lost to follow-up) (N=1)

Demographic and Clinical Characteristics at Admission

(mean ± sd)	AN Inpatient treatment N=85	AN Daypatient treatment N=87	p =
Age (years)	15.2 ± 1.5	15.3 ± 1.5	0.599
Duration of illness (weeks)	53.7 ± 39.6	42.4 ± 33.1	0.044
BMI [kg/m²]	15.1 ± 1.2	14.9 ± 1.5	0.439
BMI-percentile for age and sex	2.1 ± 4.9	1.7 ± 3.0	0.536
Binge/purging type* n (%)	14 (16.5)	17 (19.8)	0.692
Comorbidity	33 (44.0)	28 (38.4)	0.508

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Demographic and Clinical Characteristics at Discharge

(mean ± sd)	AN Inpatient treatment N=84	AN Daypatient treatment N=87	p =
Duration of treatment (days)	103 ± 41	116 ± 49	0.072
BMI [kg/m²]	17.9 ± 1.1	18.1 ± 0.9	0.20
BMI-percentile for age and sex	17.5 ± 8.3	18.6 ± 8.5	0.40
BMI-SDS	-1.0 ± 0.5	-1.0 ± 0.4	0.26

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Demographic and Clinical Characteristics at 52nd-week-follow up

(mean ± sd)	AN Inpatient treatment N=85	AN Daypatient treatment N=87
BMI [kg/m²]	17.8 ± 1.7	18.1 ± 2.0
BMI-percentile for age and sex	16.7 ± 17.0	18.6 ± 19.7
BMI-SDS	-1.3 ± 0.9	- 1,2 ± 0.9

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Intention-to-treat analysis
day patient (n=86) compared to inpatient (n=75) treatment Method

- ► **Statistical Method:** linear Model (ANCOVA) adjusting for
  - ▪ BMI
  - ▪ duration of eating disorder
  - ▪ age

  at admission

- ► **Primary Endpoint:** weight gain (delta BMI) at week 52 or at relapse

- ► **Main Results:**
  - ▪ Estimate Difference: 0.46 kg/m²
  - ▪ 95% confidence interval: (-0.12 kg/m² to 1.02 kg/m²)
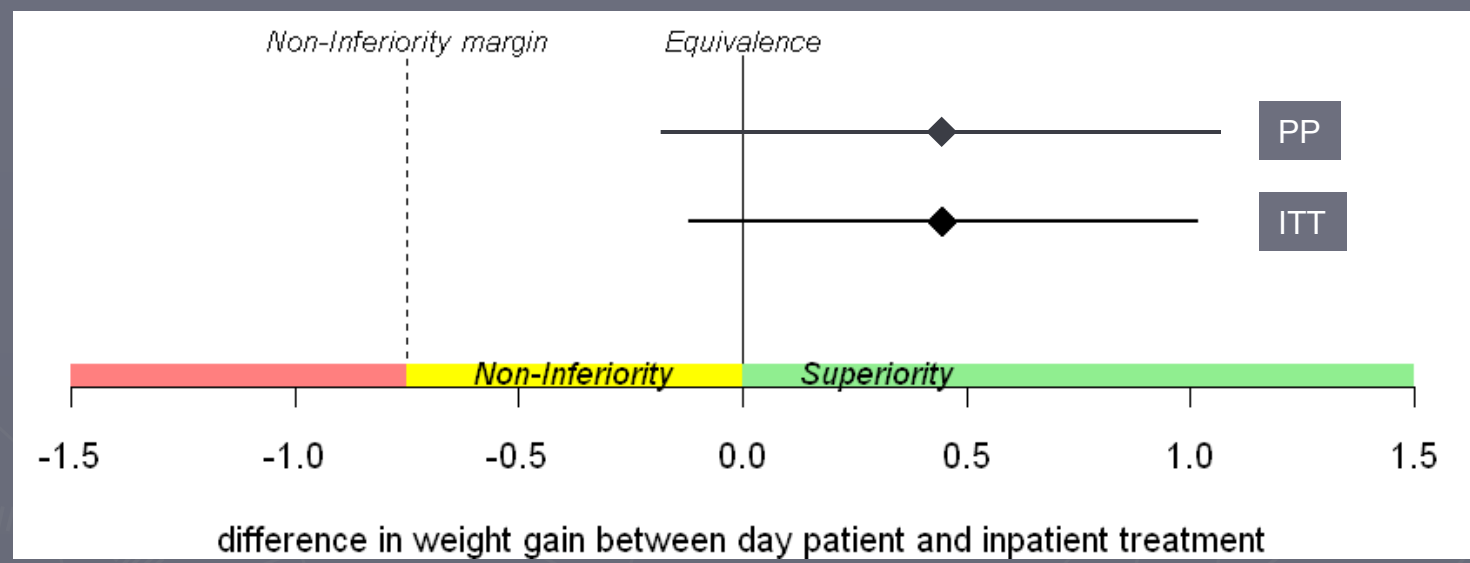
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Results: Intention-to-treat (ITT) and per-protocol analysis (PP)

Test for Non-Inferiority

p = 0.0001

Day patient treatment
is non-inferior
to inpatient treatment

Test for Superiority

p = 0.12
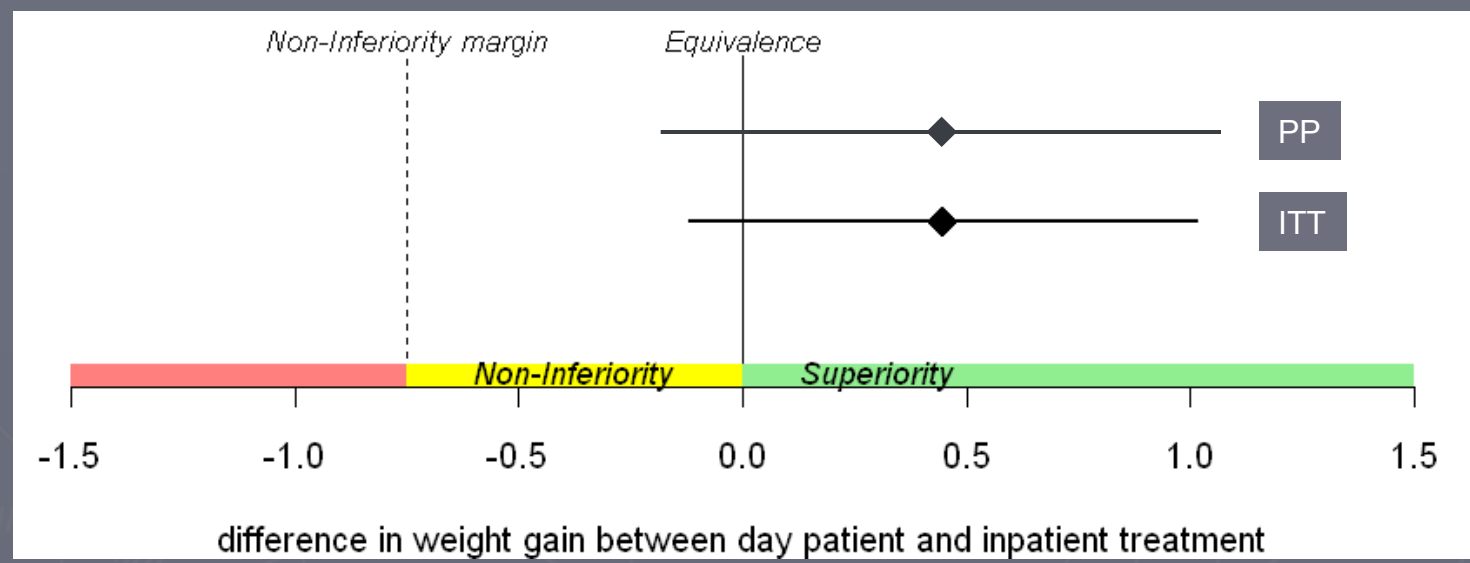
Superiority
could not be shown

Per protocol -Analysis
day patient compared to inpatient treatment

► per protocol sample including „changers": patients who completed treatment according to trial rules including those who had to change into inpatient treatment because of medical reasons or suicidality

  ▪ (IP: n=65; DP: n=70)

Estimator: 0.44 kg/m² (95%-CI: -0.17 kg/m² - 1.06 kg/m²)

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Results: Intention-to-treat (ITT) and per-protocol analysis (PP)

Test for Non-Inferiority

p = 0.0001

Day patient treatment
is non-inferior
to inpatient treatment

Test for Superiority

p = 0.12

Superiority
could not be shown

Average Outcome Score 52nd week

Average Morgan&Russell Score (MRAOS)	7.3 (2.6)	IP 69	8.4 (1.9)	DP 71	0.64 (-0.05 to 1.34)	0.07

MRAOS Subscales	IP	n= 69	DP	n= 71	CI	p=
scale A (food intake)	6.6 (3.2)		7.7 (3.1)		1.02 (-0.03 to 2.08)	0.06
scale B (menstruation)	4.2 (4.9)		4.1 (5.0)		-0.52 (-2.19 to 1.16)	0.54
scale C (mental state)	8.0 (3.1)		10.1 (2.6)		1.05 (0.09 to 2.02)	0.03
scale D (psychosexual adjustment)	7.5 (3.5)		9.1 (2.7)		1.29 (0.34 to 2.24)	0.008
scale E (socio-economic state)	9.8 (2.1)		10.5 (1.5)		0.46 (-0.12 to 1.04)	0.12

Drop out of treatment and drop out of study and Relapses in ITT-Sample

Drop out of treatment: 20%
- IP: 10 (out of 85):   12%
- DP: 25 (out of 87):   29%

Drop out of study at 52nd week follow-up: 7%
- IP: 10 (out of 85):   12 %
- DP: 1 (out of 87):   1 % $p < 0.005$

Relapses at 52nd week follow-up: 19%
- IP: 19 (out of 75):   25 %
- DP: 13 (out of 86):   15 % $p < 0.12$

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Costs

Costs (€)	IP Mean (sd)/number (%)	N	DP Mean (sd)/number (%)	N	P-value
	39.481 € (± 16174) (33.788 ± 13.842 £)	85	31.114 € (± 16.246) (26.628 ± 13.903 £)	87	0.002

Serious Adverse Events

	IP	DP
During treatment		
Suicidal ideation	1	1
Intensive treatment because of complete refusal of eating		1
Appendectomy		1
After discharge		
Suicidal ideation	2	
IP for depression	2	2
Somatic problems (circulatory collapse)	1	
Appendectomy	1	
Suicide attempt		1

Conclusion I

1. In a large randomized multisite trial after short medical stabilization DP was as effective as IP in young non-chronic AN;

2. superiority of day patient treatment just missed significance;

3. patients in the DP-group were more compliant;

4. Psychosocial outcome tended to be better in DP;

Conclusion II

► Stepped-care DP resulted in a mean insurance cost savings of 20%;

► Considering the developmental significance of adolescence, treatment options facilitating autonomy and self-confidence should be supported;

► Investigation of 2.5-year- follow-up is still going on.

And the parents and patients?

► „It is wonderful being at home in the evening together with my family and friends…"

► „Eating at home is much more comfortable and relaxing…"

► „It was so good that our daughter was at home – although it was hard for us…"

► „It was good that our daughter could keep her personal contacts and friends…she was never lonely…"

► „(During DP) she got much more independent and self-conscious than ever before…"

► „DP was the best that could happen to her – it was like getting six numbers right in the lottery…"

Comparison of inpatient and day-patient treatment in adolescent anorexia nervosa

Thanks to

► A. Dempfle, Statistician, Marburg

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- B. Müller, MD, Düren

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R. Schwarte, K. Bühren, M. Krei, U. Hagenah, U. Thevissen, K. Konrad
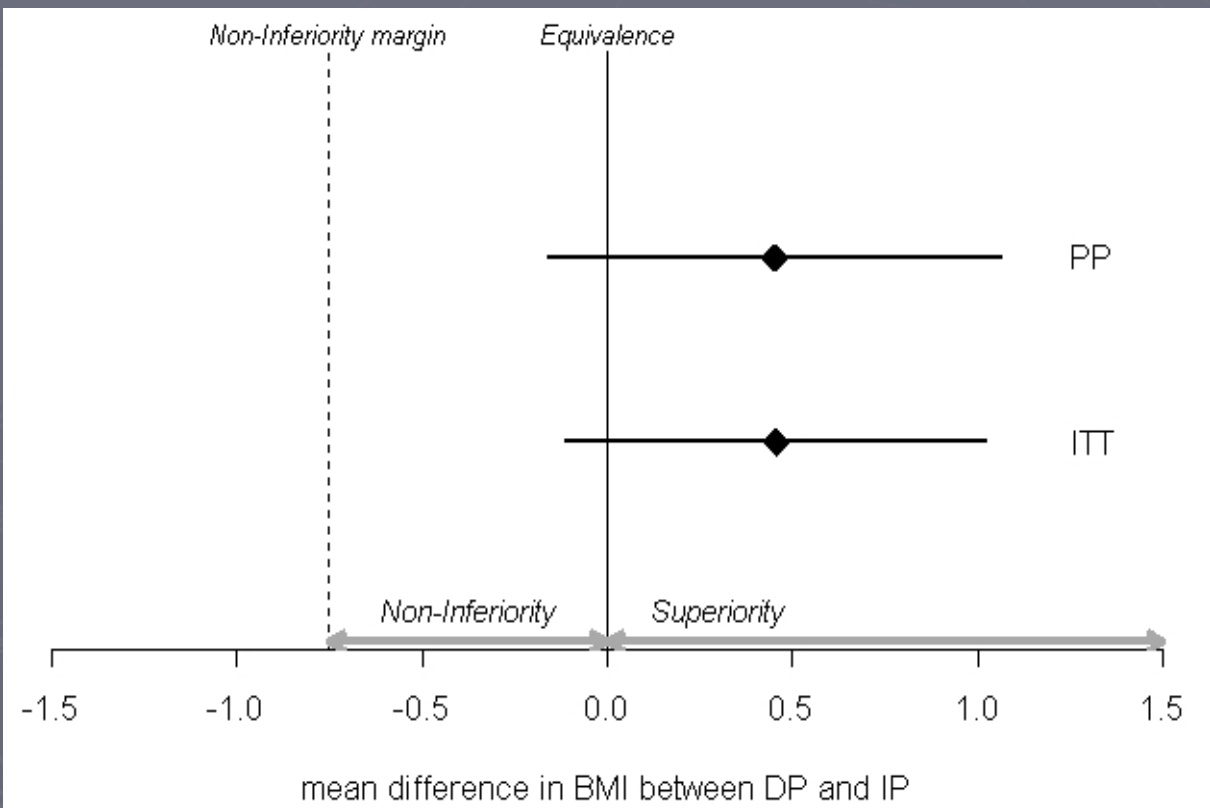
Thank you
for your attention.

And of course to all the patients and parents!

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Results
Comparison of Intention-to-treat analysis (DP (n=86)/ IP (n=75) and per protocol analysis including changers (PPS1) and without changers (PPS2)

And the parents and patients?
Critical voices…

► "Everything at home remembers me of my old anorexia: the table, the fridge, it is a great effort…"

► "At the beginning I did not know whether to be happy or unhappy (about day patient treatment): it was so difficult at home…"

► "The disadvantage of day patient treatment is that you can do so much more in secret: running, exercising, skipping meals…"

► "We, the family, definitely had to realize that our daughter was so ill …"

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