NG TUBE FEEDING FOR HYPEREMESIS GRAVIDARUM

THE MOTHER TRIAL

Rebecca Painter

On behalf of Iris Grooten, Marjette Koot and the MOTHER Study Group

Mother

amc

nvog consortium 2.0

Foreest Medical School

COI disclosure

- Declaration of interests: receive funding from AMC-VU; ZonMw; Netherlands Heart Foundation
- Financial support by Foreest Medical School
- Dutch Trial Register NTR4197

nvog consortium 2.0

Pre study situation in the Netherlands

- No national guideline for HG
- Most obstetricians would only consider NG tube feeding in extreme HG (several readmissions, marked weight loss) and only in an inpatient setting.
- Corticosteroids for HG rare
- Daycare/home care HG rare

Why NG tube feeding for HG?

"I think if they had started earlier with rehydration and nasogastric tube feeding, the harm would have been in any case limited; I wouldn't have lost so much weight and wouldn't have been lagging behind so much."

"The nasogastric tube feeding provided (….) a constant intake. (…) So my stomach stayed quite calm, so I didn't vomit and could take in the nutrients. But in my first pregnancy (….), I was so extremely weak after giving birth, because I hadn't taken and absorbed any nutrients. Because I received nasogastric tube feeding during my second pregnancy, I just noticed that it went so much better."

van Vliet et al, submitted

nvog consortium 2.0

Why NG tube feeding for HG?

- 2 women with HG, avoided intravenous feeding
- 7 women with HG, all improved <24 h after NG tube placement. Continued tube for 43 days
- 30 women with HG 'dramatic improvement' within 1-2 hrs.

Hsu et al 1996;Gulley 1993; Pearce 2001

Why NG tube feeding for HG?

- HG associated with poor perinatal outcome
- This may be mediated by poor maternal weight gain
- Effects health offspring?
- And feeding is *not* a part of treatment HG

Veenendaal et al, Dodds et al, Ayyavoo et al, Roseboom et al, Green Top Guideline RCOG 2016

nvog consortium 2.0

Objective

- To assess whether **early** enteral tube feeding in addition to standard care is a more effective treatment for HG than standard care alone, and results in improved maternal and neonatal outcomes

MOTHER

Maternal and **O**ffspring outcomes
after **T**reatment of **H**yper**E**mesis by **R**efeeding

Mother

www.studies-obsgyn.nl/Mother

nvog consortium 2.0

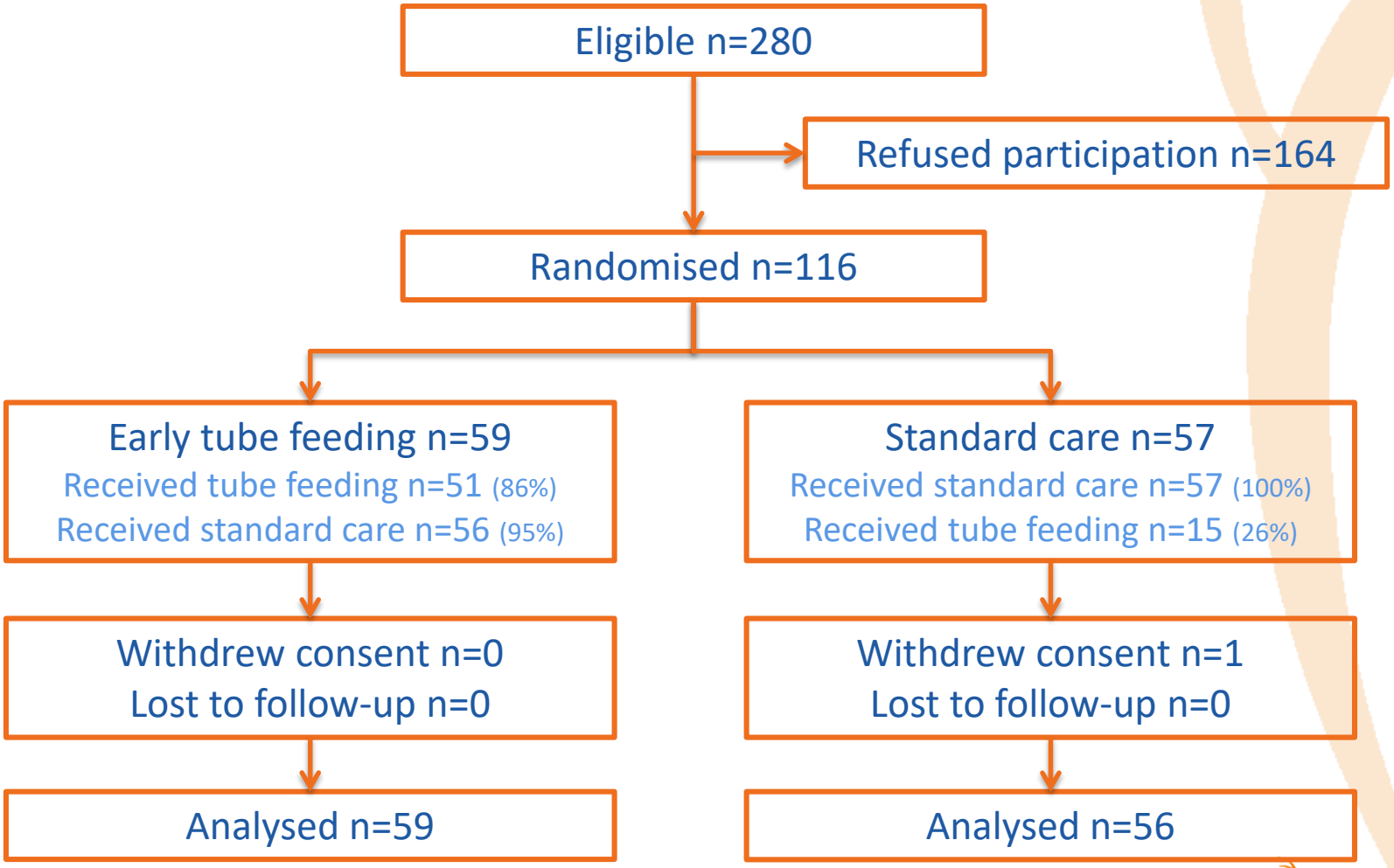
Design

- A multicenter open-label randomised controlled trial (19 centres)
- Women hospitalised for HG between 5 and 20 weeks gestation
- Random allocation to:
  - Enteral tube feeding ≥7 days in addition to standard care with i.v. rehydration and antiemetic treatment
  - Standard care

Outcomes

- Primary outcome
  - Birthweight
- Secondary maternal outcomes
  - maternal weight gain
  - duration of hospital stay, readmission rate
  - nausea and vomiting symptoms (PUQE-24)
  - quality of life and psychological distress (NVPQoL)
- Secondary neonatal outcomes
  - Prematurity (birth <37 weeks gestation)
  - Small for gestational age (birth weight ≤p10)
  - Apgar score <7 at 5 minutes

Participant selection



nvog consortium 2.0

Table 1 – Baseline characteristics

Characteristics	Early tube feeding (n=59)	Standard care (n=56)
Age at inclusion (years)	28.2±5.0	28.7±4.6
Primigravida	19(32%)	17(30%)
Western ethnicity	34(58%)	34(67%)
Pre-pregnancy weight (kg)	72.8±16.7	69.8±14.6
Weight loss at inclusion (kg)	-2.5±4.3	-4.3±4.1
Gestational age at inclusion (weeks)	9±3	9±3
HG in previous pregnancy	18 (31%)	23(41%)
HG in previous pregnancy requiring hospital admission*	45%	59%
Total PUQE score	11.5±3.0	10.4±3.0

Data represent mean±SD or number(%)
* % of women with a previous pregnancy

nvog consortium 2.0

Table 2 – Primary outcome

Outcome	Early tube feeding (n=60)	Standard care (n=55)	P-value
Birth weight (g)	3160±770	3200 ±681	.79

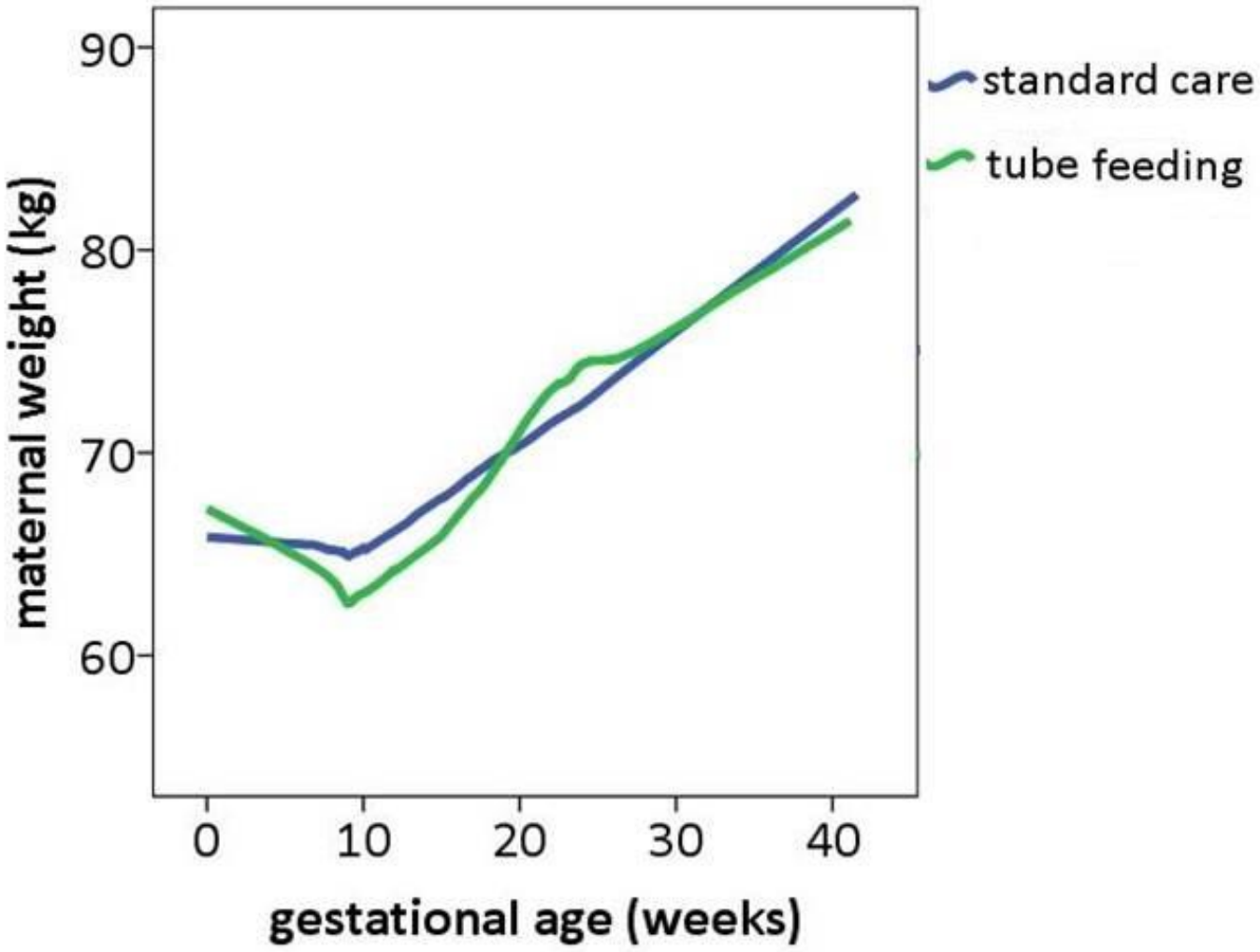
Data represent mean±SD

Table 3 – Maternal Neonatal outcomes

Maternal outcomes	Early tube feeding (n=59)	Standard care (n=56)	P-value
Total days of admission	4(3-5)	4(3-5)	.53
Readmission for HG	22 (38%)	20 (37.0%)	.92
1 week after randomisation			
Δ PUQE	-2.2±3.1	-1.1±3.5	.26
Δ NVPQoL	-14.1±26.7	-30.2±37.6	.09
Δ weight (kg)	0.6 ± 4.2	-0.5 ± 2.6	.18
3 weeks after randomisation			
Δ PUQE	-2.6±3.8	-2.3±4.0	.82
Δ NVPQoL	-25.0±44.8	-43.6±41.2	.15
Δ weight (kg)	0.9 ± 4.7	-0.1 ± 3.6	.35
Neonatal outcomes			
Gestational age (weeks)	39 (38-40)	39 (37-40)	.58
Small for gestational age	5(9%)	4(7%)	.82
Prematurity	7(12%)	7(13%)	.89
Apgar score <7 at 5 minutes	5(8%)	2(4%)	.29

Data represent mean±SD, median(IQR) or number(%)

nvog consortium 2.0



nvog consortium 2.0

Table 4 – Side-effects

	Early tube feeding (n=59)	Standard care (n=56)	P-value
Side effects intravenous rehydration			
- Phlebitis	2(3%)	1(2%)	.59
- Pain	1(2%)	1(2%)	.97
Side effects tube feeding			
- Nose throat irritation	26 (44%)	5(9%)	<0.001
- Obstruction	3(6%)	0	.09
- Tube dislodgement	23(39%)	9(16%)	.01

Data represent in number(%)

nvog consortium 2.0

Table 5 – SAE's

Maternal SAE's	Early tube feeding (n=59)	Standard care (n=56)	P-value
- Maternal death	0	0	-
- Complications tube feeding			
Aspiration	0	0	-
Intestinal bleeding	0	0	-
Perforation	0	0	-
Neonatal SAE's			
- Perinatal death	2(4%)	0	.39
- Birth defect	0	0	-
- NICU admission	2(4%)	1(2%)	.61

Data represent mean±SD, median(IQR) or number(%)

nvog consortium 2.0

Per protocol analysis

- 48% of those randomised to NG tube received treatment per protocol
  - 7% declined NG tube insertion
  - 34% had NG tube removed due to discomfort/side effects

- Per protocol analyse
  - NG tube feeding n=28
  - Standard treatment n=48

Per protocol analysis

- Neonatal
  - No difference in outcomes
- Maternal
  - No difference in in PUQE score, weight, duration of admission, or readmissions.
  - 1 and 3 weeks after inclusion, NVP quality of life had improved ***less*** after NG tube feeding compared to standard treatment

Per protocol

Primary outcome

	Early tube feeding (n=28)	Standard treatment (n=48)	P
Birth weight(g)	3200±930	3320 ±440	.57

Secondary outcomes

Maternal			
Total days of admission (d)	4(3-6)	4(3-5)	.99
Readmission for HG	46%	18%	.01
1 week after randomisation			
Δ Weight (kg)	0.5±4.3	-0.8±2.0	.23
Δ PUQE-24	-2.0±2.7	-0.7±3.3	.14
Δ NVPQoL	-6.0±13.0	-34.0±41.0	.01
3 week after randomisation			
Δ Weight (kg)	0.8±4.9	-0.9±3.6	.22
Δ PUQE-24	-1.4±3.6	-2.8±4.2	.52
Δ NVPQoL	-9.0±33.0	-44.0±40.0	.01
Neonatal			
Gestational age (weeks)	39(38-40)	39(38-40)	.72
Small for gestational age	8	3	.33
Prematurity (<37 wk)	18	10	.37

consortium 2.0

Conclusion

- Early enteral tube feeding in addition to standard care does not improve symptoms or perinatal outcomes in comparison to standard care alone, in women admitted to hospital for HG.

Discussion

- Participants did not tolerate NG tube well
  - 7% refused tube placement at randomisation
  - Side-effects frequently reported
  - Early tube removal due to side-effects in 28%
- Unclear whether deferred tube feeding is benificial in women with severe HG

Lessons learned

- Despite preperation: frequent refusal/ early rejection NGtube
- Early involvement of patients in protocol development
  - How to measure sequential PUQE, NVPQoL, HIS etc during HG?

What's next: MOTHER 2/3/4

- Research priorities by all stakeholders
- Solid methology of multicentre RCT
- Definition of HG, core outcomes,
- Definition *severe* HG
- H Pylori? Corticosteroids? Self-management anti emetics?

nvog consortium 2.0