

The effect of plasma donation frequency on plasma proteins

- Preliminary Results from a Randomized Controlled Trial

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Disclosures

No conflict of interest to declare.



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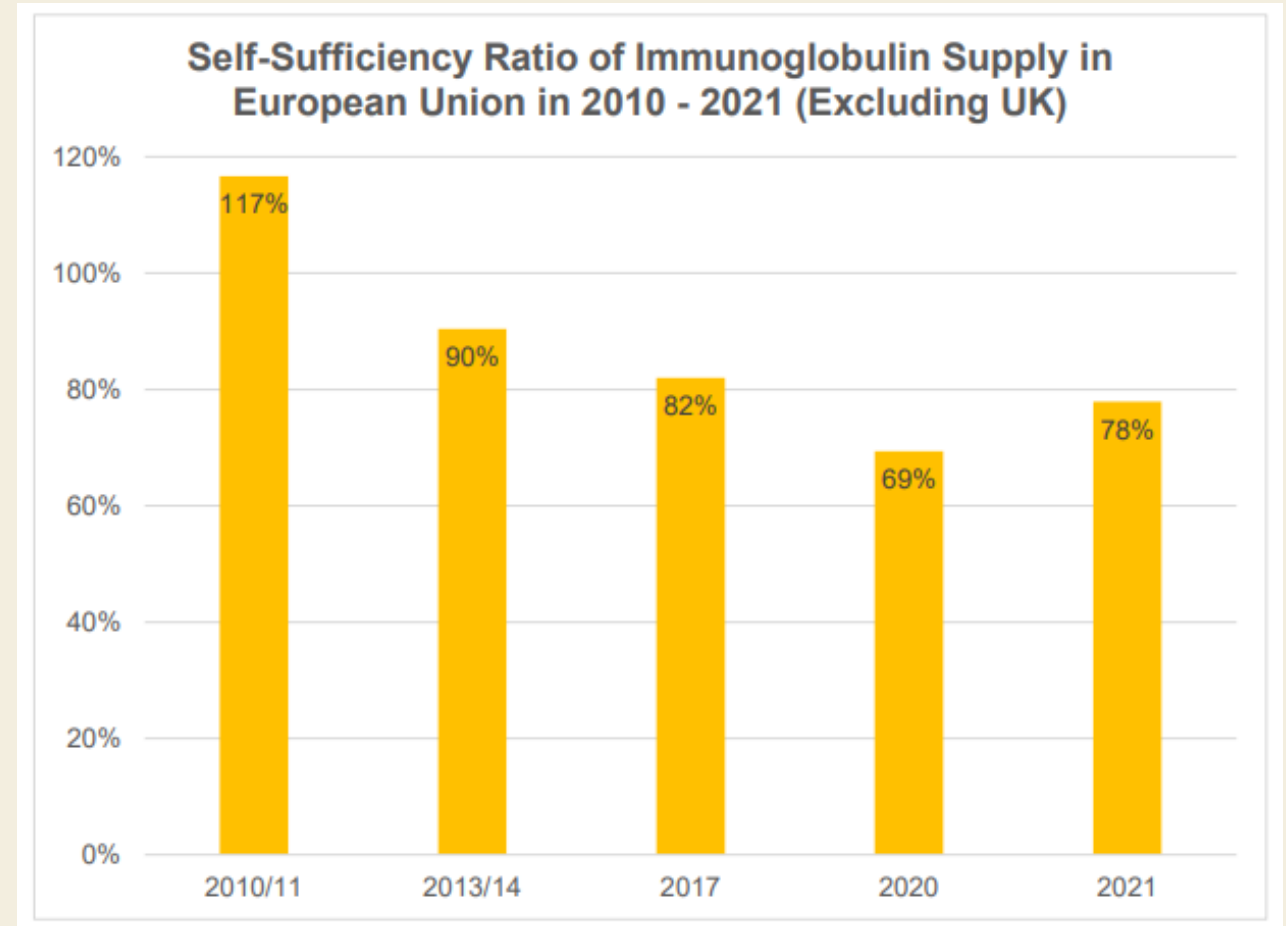


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Background

- The demand for plasma derived medicinal products (PDMPs) is increasing globally and it has exceeded the supply of plasma



Background

- To meet this growing demand of PDMPs, plasma collection must be increased
- When increasing either plasma donation volume or frequency, we need to ensure donor health



Background

REVIEW

Vox Sanguinis  International Society of Blood Transfusion

Safety and protection of plasma donors: A scoping review and evidence gap map

Natalie Schroyens^{1,2} | Tine D'aes¹  | Emmy De Buck^{1,2}  | Susan Mikkelsen³ |
Pierre Tiberghien^{4,5}  | Katja van den Hurk^{6,7}  | Christian Erikstrup^{3,8} |
Veerle Compennolle^{9,10} | Hans Van Remoortel^{1,2} 

Conclusion: The current scoping review provides an accessible tool for researchers and policymakers to identify the available evidence (gaps) concerning plasmapheresis donation safety. Controlled prospective studies with long-term donor follow-up are scarce. Furthermore, additional experimental studies comparing the health effects of different donation frequencies are required to inform a safe upper limit for donation frequency.

Aim

Plasma donation
frequency



Donor health



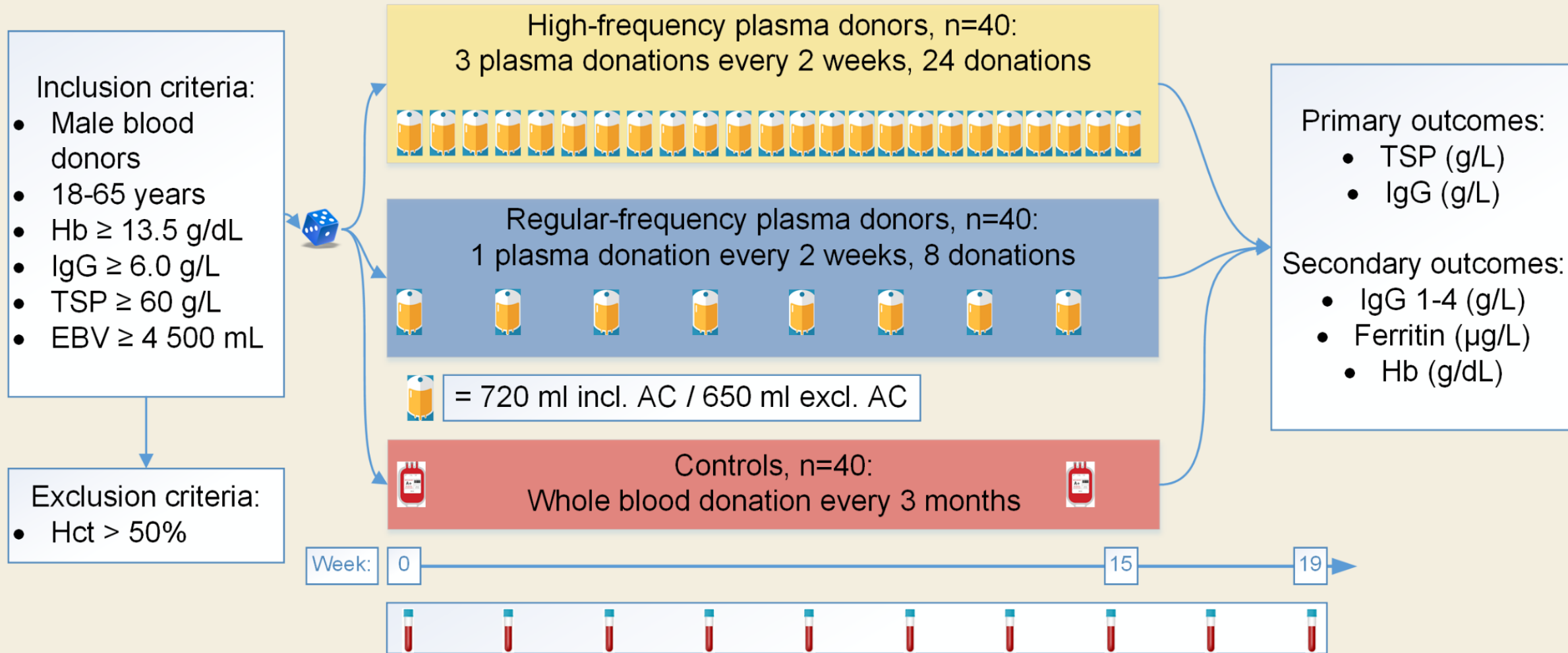
Total serum protein
(TSP)

Immunoglobulin G (IgG)
and IgG subclasses

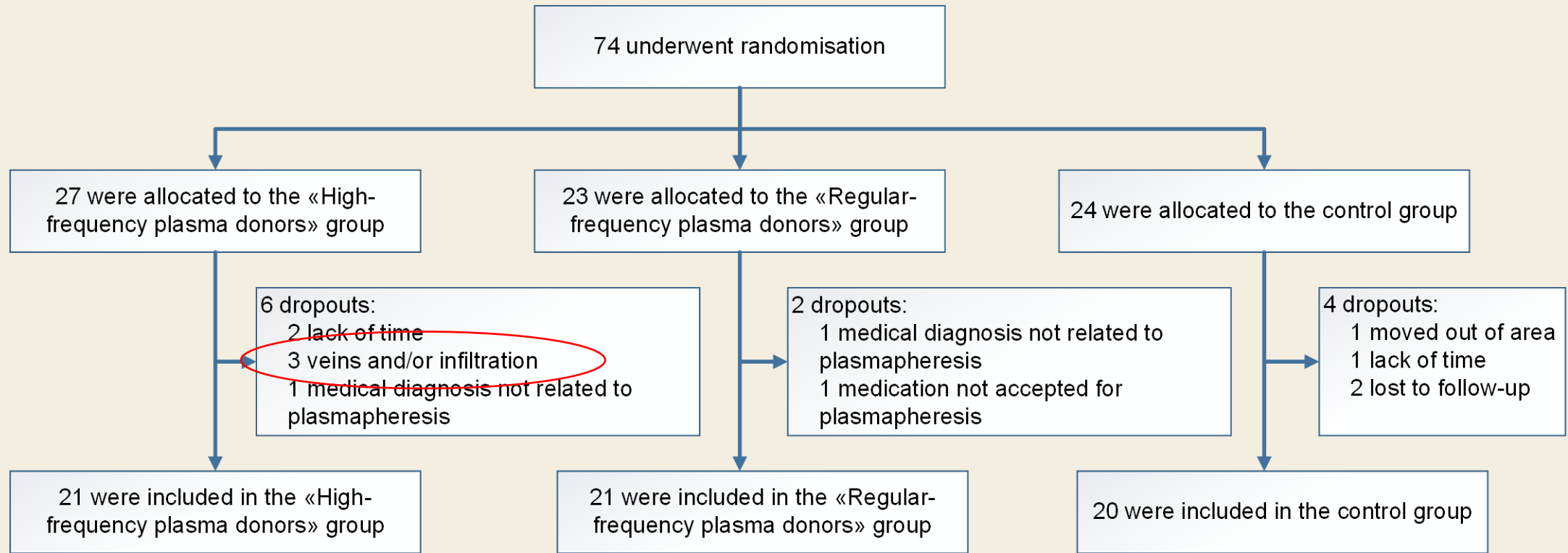
Haemoglobin, ferritin



Method



Results: Flow-chart and drop-outs



Results: Baseline characteristics

	High-frequency plasma donors, n=21	Regular-frequency plasma donors, n=21	Controls, n=20
Age (years)	45.8 (10.7)	47.8 (8.9)	49.0. (12.0)
Height (cm)	184.5 (6.7)	183.6 (7.0)	182.9 (6.1)
Weight (kg)	92.5 (15.1)	93.6 (14.3)	91.3 (9.2)
TSP (g/L)	70.6 (3.9)	70.2 (3.8)	70.1 (3.9)
IgG (g/L)	10.8 (2.1)	10.0 (2.0)	10.5 (1.6)
Hb (g/dL)	15.0 (0.8)	15.1 (0.6)	15.5 (0.9)
Ferritin (µg/L)	58 (35-76)	51 (44-69)	64 (37-80.5)
EBV (mL)	5,786.3 (567.9)	5,796.8 (554.0)	5,709.7 (322.0)

Results: Donations completed in 16 weeks

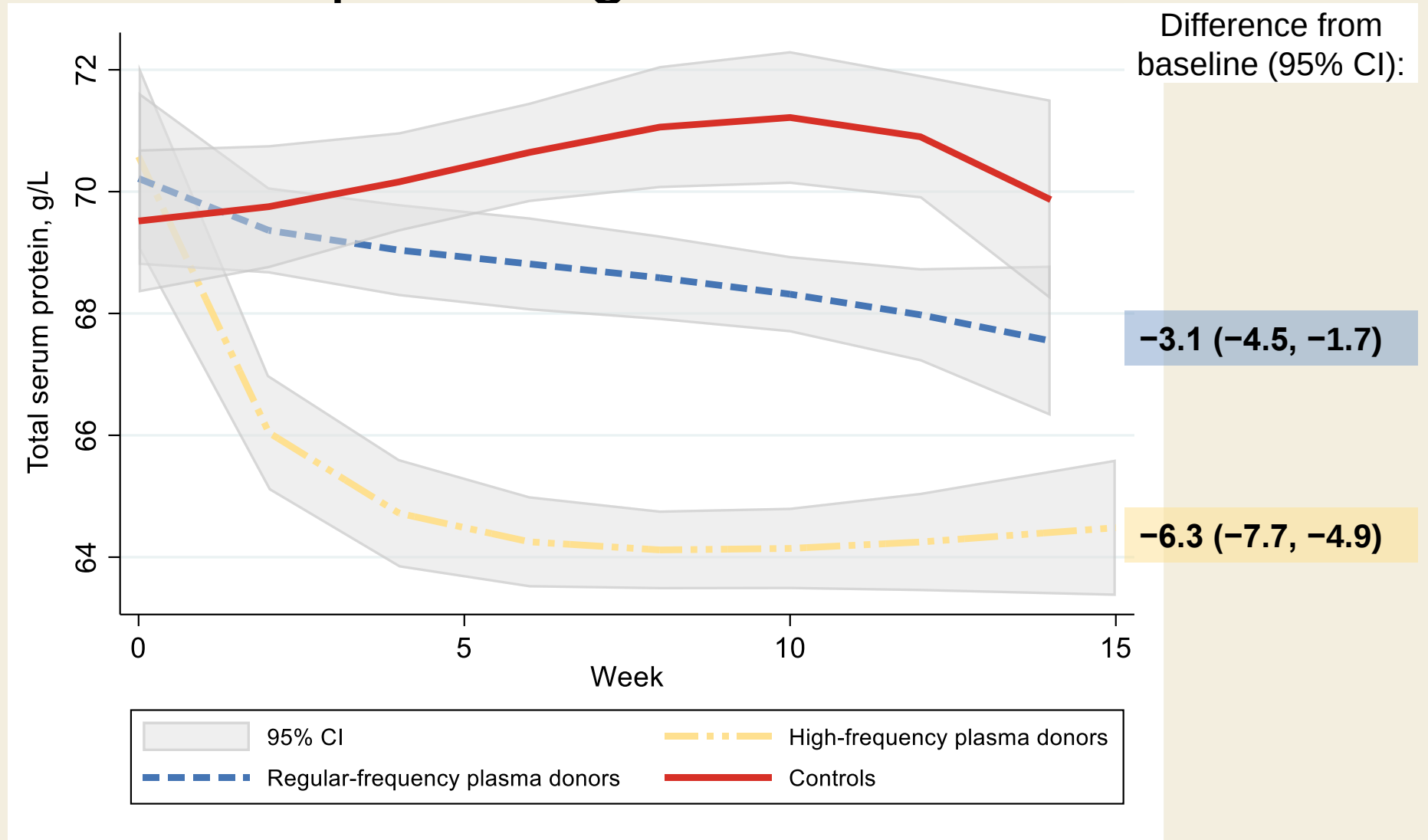
Donations	High-frequency plasma donors, n=21	Regular-frequency plasma donors, n=21	Controls, n=20
Plasma	22 (14-24) of 24 planned	8 (3-8) of 8 planned	
Whole blood			2 (1-2) of 2 planned

Results: Temporarily deferral

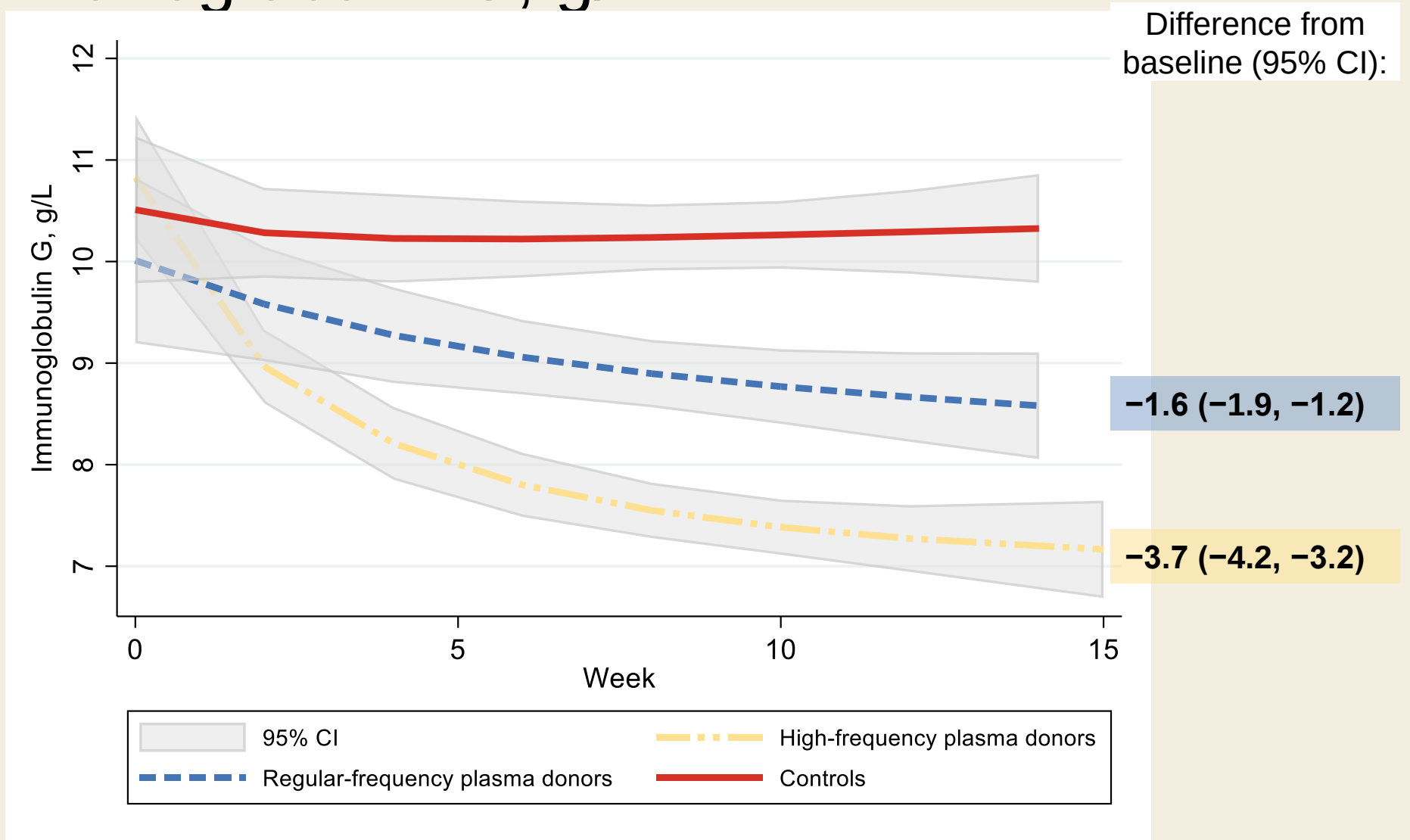
If the donors had TSP < 60 g/L and/or IgG < 6.0 g/L, they were temporarily deferred and did not donate plasma for at least 2 weeks.

	High-frequency plasma donors, n=21	Regular-frequency plasma donors, n=21
No deferral	17	20
Temporarily deferral	4	1
Duration of deferral	2-6 weeks	8 weeks

Results: Total serum protein, g/L

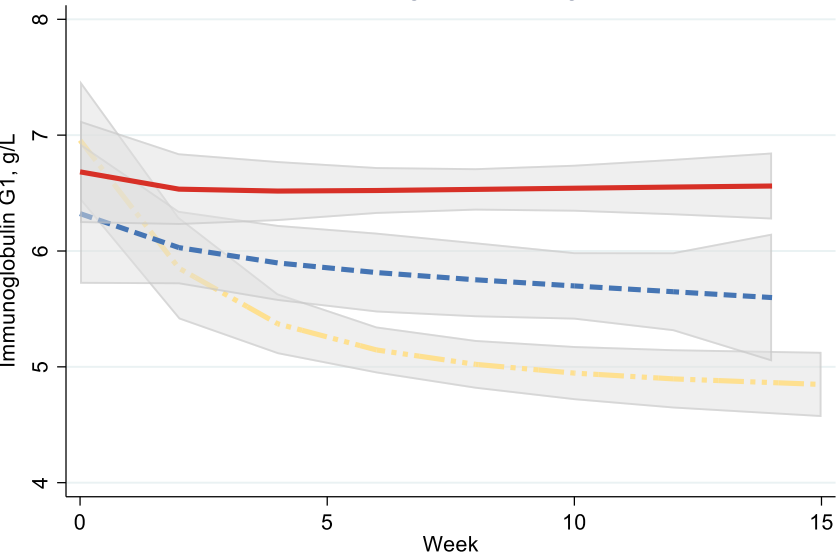


Results: Immunoglobulin G, g/L



Results: Immunoglobulin G subclasses 1-4, g/L

Immunoglobulin G1, g/L

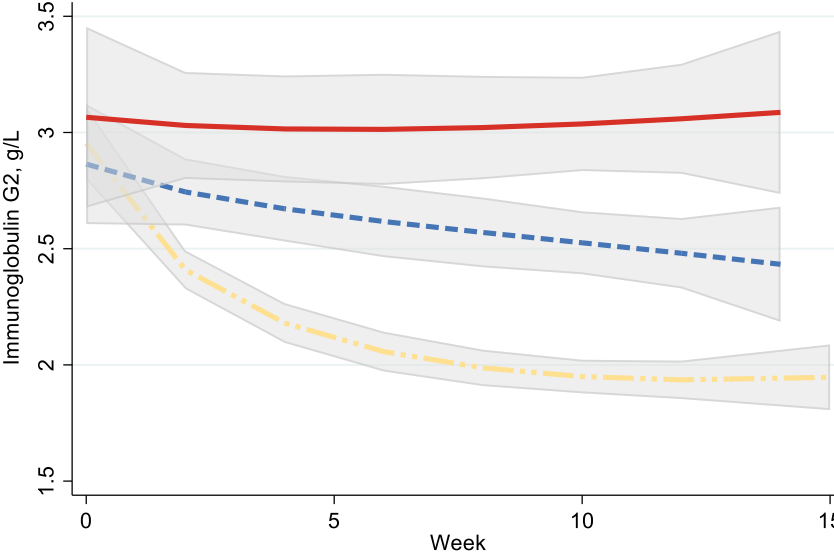


Difference from baseline (95% CI):

-0.8 (-1.1, -0.6)

-2.1 (-2.5, -1.8)

Immunoglobulin G2, g/L

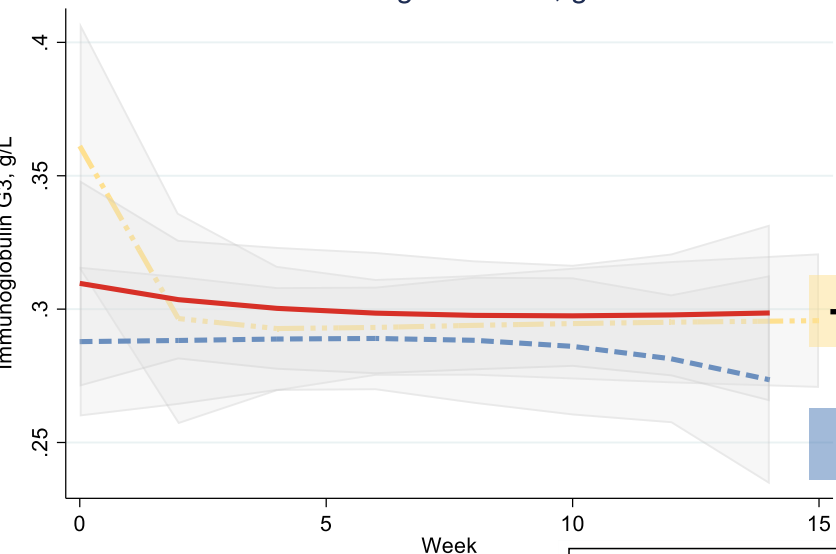


Difference from baseline (95% CI):

-0.5 (-0.6, -0.3)

-1.0 (-1.2, -0.9)

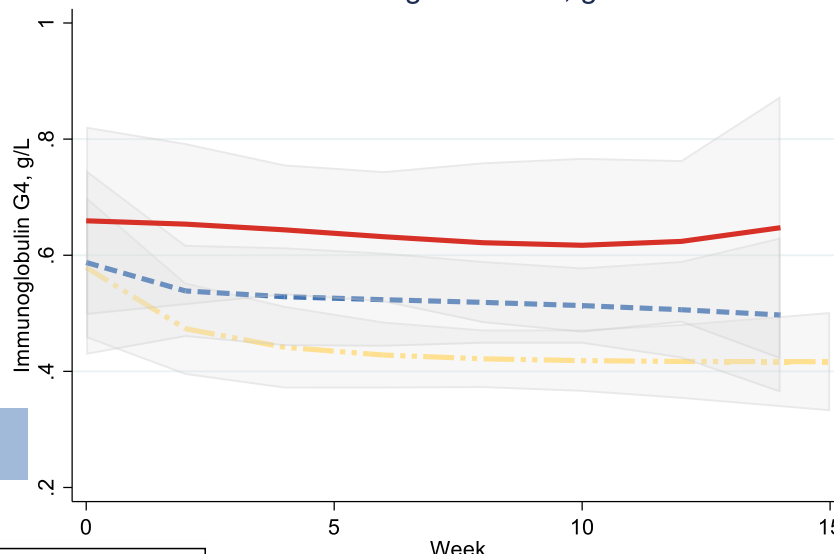
Immunoglobulin G3, g/L



-0.07 (-0.09, -0.05)

-0.03 (-0.04, -0.007)

Immunoglobulin G4, g/L

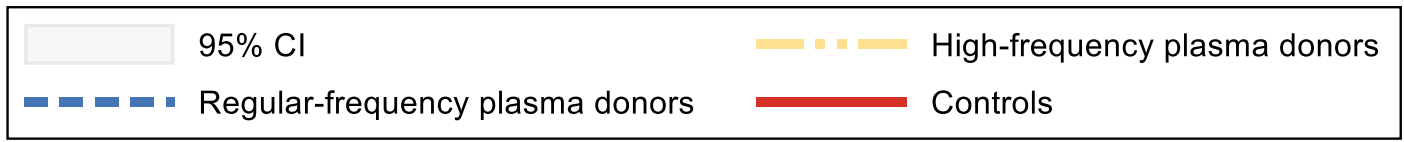
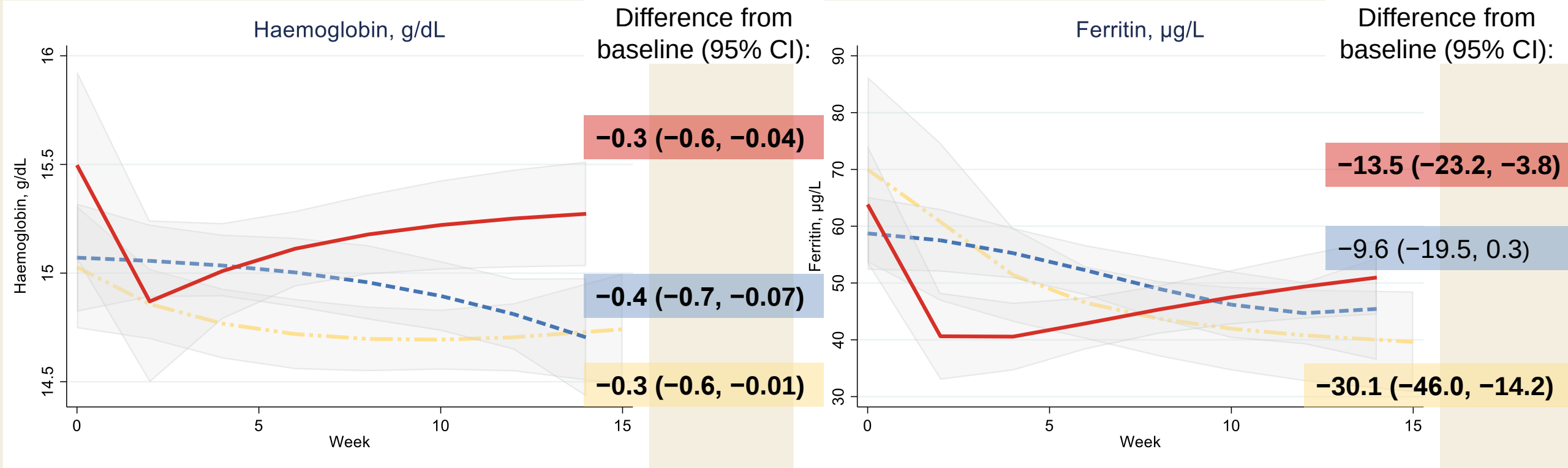


-0.1 (-0.2, -0.02)

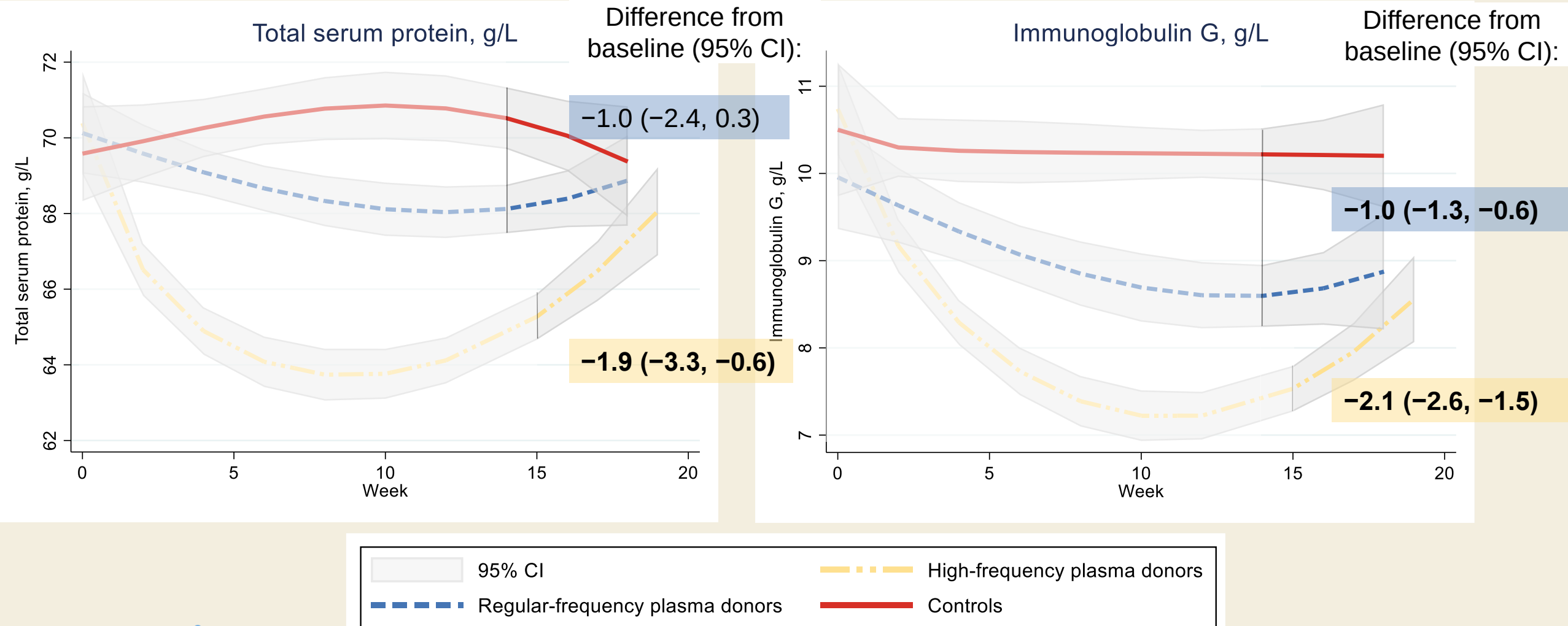
-0.2 (-0.2, -0.1)



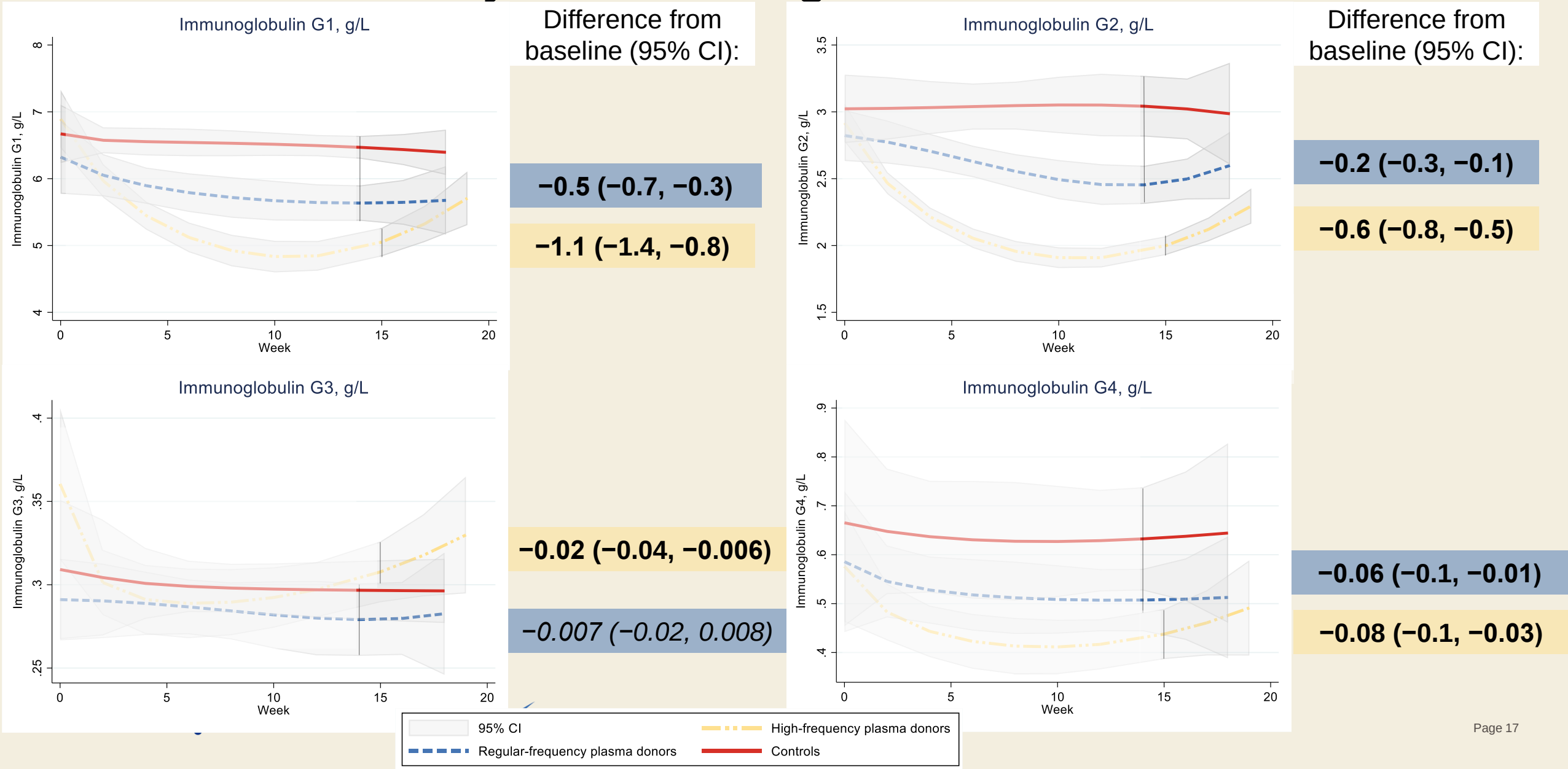
Results: Haemoglobin and ferritin



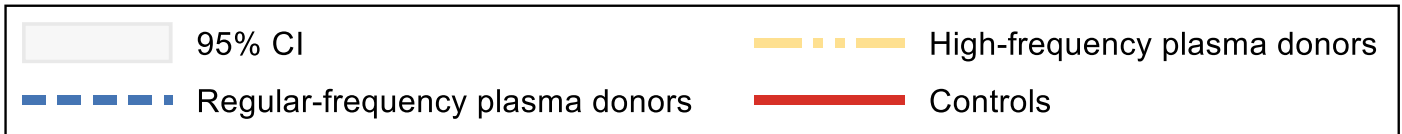
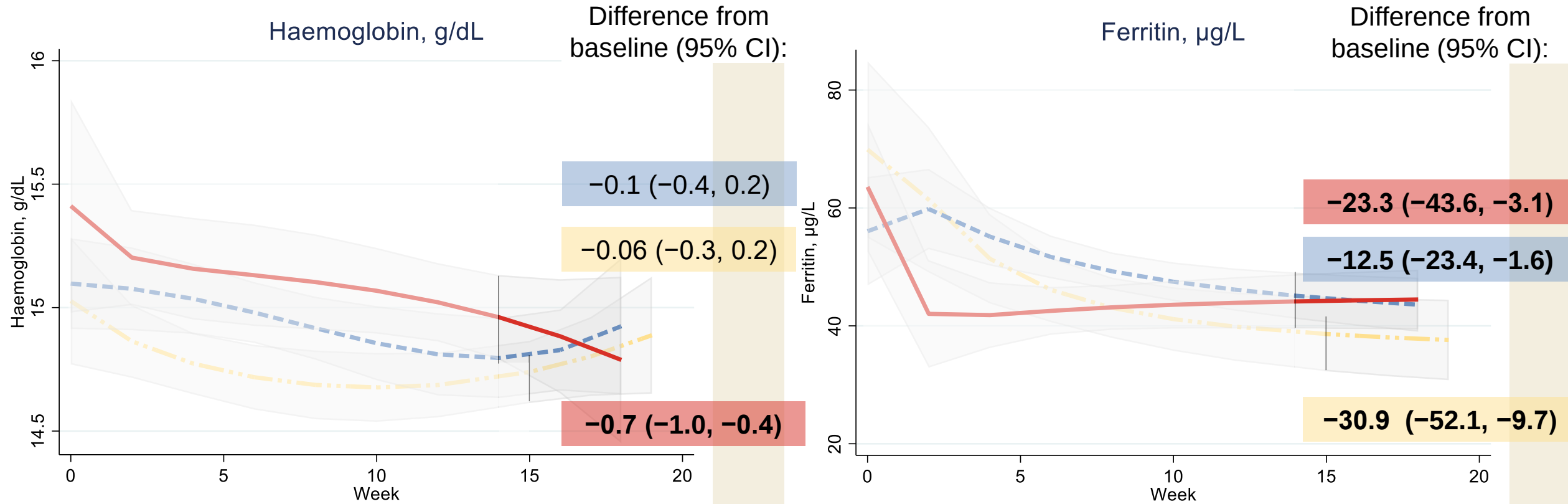
Results: Recovery of TSP and IgG after donations



Results: Recovery of immunoglobulin G subclasses 1-4



Results: Recovery of haemoglobin and ferritin after donations



Summary and conclusions

- Concentrations of **TSP, IgG incl. subclasses, Hb and ferritin** were **significantly reduced** in both high-frequency and regular-frequency plasma donors after 16 weeks
 - The degree of reduction increased with higher donation frequency
- The **recovery** of most of these plasma proteins to baseline levels **took more than 4 weeks** after donations
- The long-term health consequences of these findings need to be further addressed

Implications:

- **Protein yield** for plasma fractionation may **decrease** with increasing donation frequency
- **Longer plasma donation intervals, more than 2 weeks, are suggested**, to ensure a sustainable plasma supply and the health of long-term plasma donors

Thank you

The research group:

- Karin Magnussen, Department of Immunology and Transfusion Medicine, Innlandet Hospital Trust
- Lise Sofie Haug Nissen-Meyer, Department of Immunology, Oslo University Hospital
- Tor A. Strand, Department of Research, Innlandet Hospital Trust

The blood donors

Donation sites Elverum, Gjøvik, Hamar and Lillehammer at Innlandet Hospital Trust

Results: Recovery of plasma proteins 2 and 4 weeks after donations

Mean difference from baseline, g/L (95% CI)	High-frequency plasma donors, n=21		Regular-frequency plasma donors, n=21		Controls, n=20	
	2 weeks	4 weeks	2 weeks	4 weeks	2 weeks	4 weeks
TSP	-4.5 (-6.2 - -2.9)	-1.9 (-3.3 - -0.6)	-1.9 (-3.5 - -0.2)	-1.0 (-2.4-0.3)	-0.05 (-1.5 - 1.4)	-0.5 (-2.3-1.4)
IgG	-3.0 (-3.4 - -2.5)	-2.1 (-2.6 - -1.5)	-1.6 (-1.9 - -1.3)	-1.0 (-1.3 - -0.6)	-0.5 (-0.9 - -0.1)	-0.2 (-0.6-0.2)
IgG1	-1.7 (-2.1 - -1.4)	-1.1 (-1.4 - -0.8)	-0.8 (-1.0 - -0.6)	-0.5 (-0.7 - -0.3)	-0.4 (-0.6 - -0.1)	-0.3 (-0.5 - -0.07)
IgG2	-0.9 (-1.0 - -0.7)	-0.6 (-0.8 - -0.5)	-0.4 (-0.5 - -0.3)	-0.2 (-0.3 - -0.1)	-0.04 (-0.1 - 0.03)	-0.06 (-0.1 - 0.02)
IgG3	-0.05 (-0.07 - -0.03)	-0.02 (-0.04 - -0.006)	-0.02 (-0.04 - -0.004)	-0.007 (-0.02 - 0.008)	-0.01 (-0.03 - 0.009)	-0.01 (-0.04 - -0.006)
IgG4	-0.1 (-0.2 - -0.08)	-0.08 (-0.1 - -0.03)	-0.1 (-0.2 - -0.03)	-0.06 (-0.1 - -0.01)	-0.02 (-0.07 - 0.2)	-0.02 (-0.06 - 0.01)
Hb	-0.3 (-0.6 - -0.03)	-0.06 (-0.3 - 0.2)	-0.2 (-0.5 - 0.1)	-0.1 (-0.4 - 0.2)	-0.9 (-1.2 - -0.7)	-0.7 (-1.0 - -0.4)
Ferritin	-36.7 (-54.1 - -19.3)	-30.9 (-52.1 - -9.7)	-10.3 (-18.6 - -2.0)	-12.5 (-23.4 - -1.6)	-30.8 (-41.0 - -20.5)	-23.3 (-43.6 - -3.1)