

Appendix I

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Figure 1. Abbreviated Mevalonate Pathway.

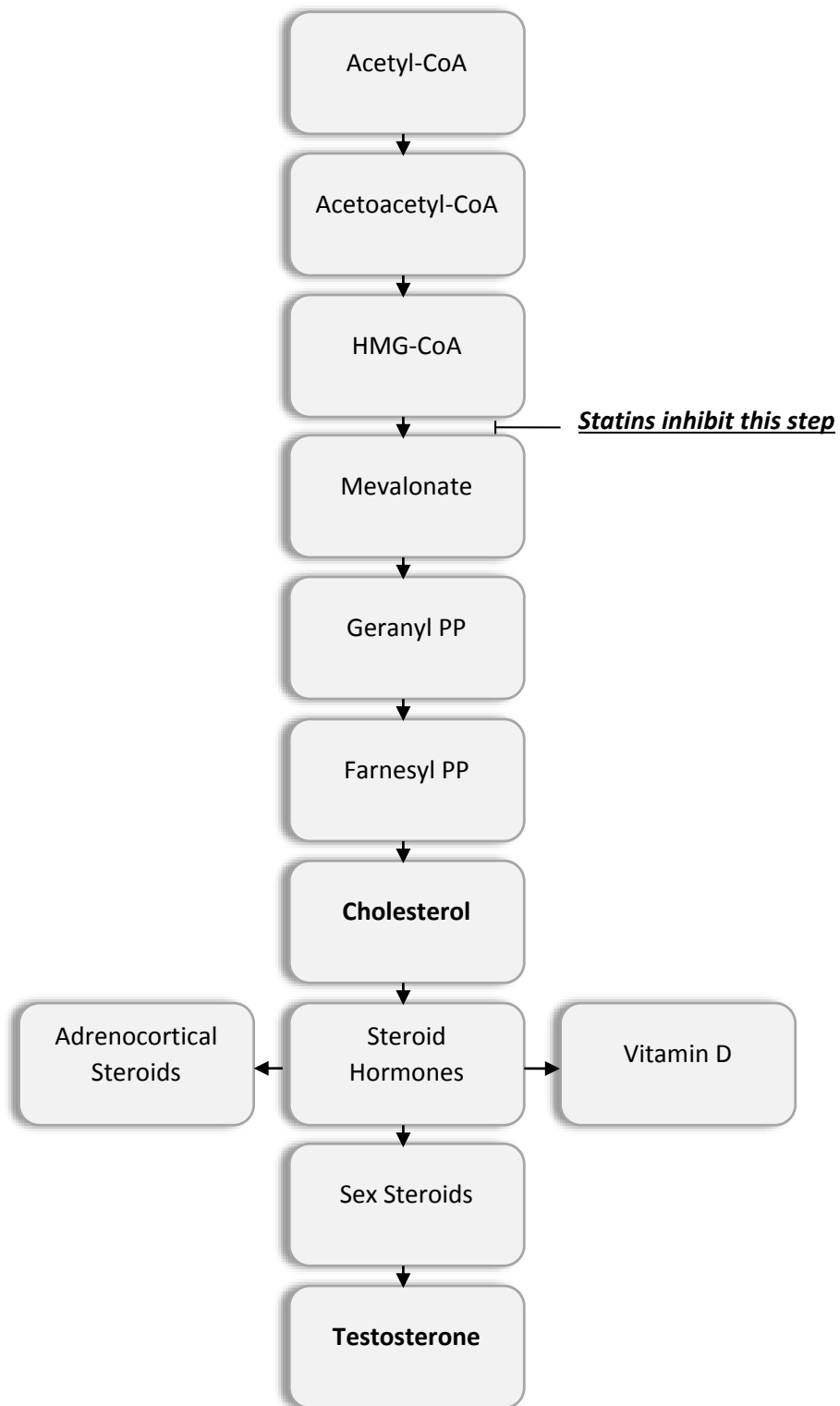


Figure 1 legend. Depicts site of inhibition by statins; shows cholesterol and testosterone as products of the affected pathway.

Figure 2. Consort Flow Diagram: Combined Sample (Men & Women).

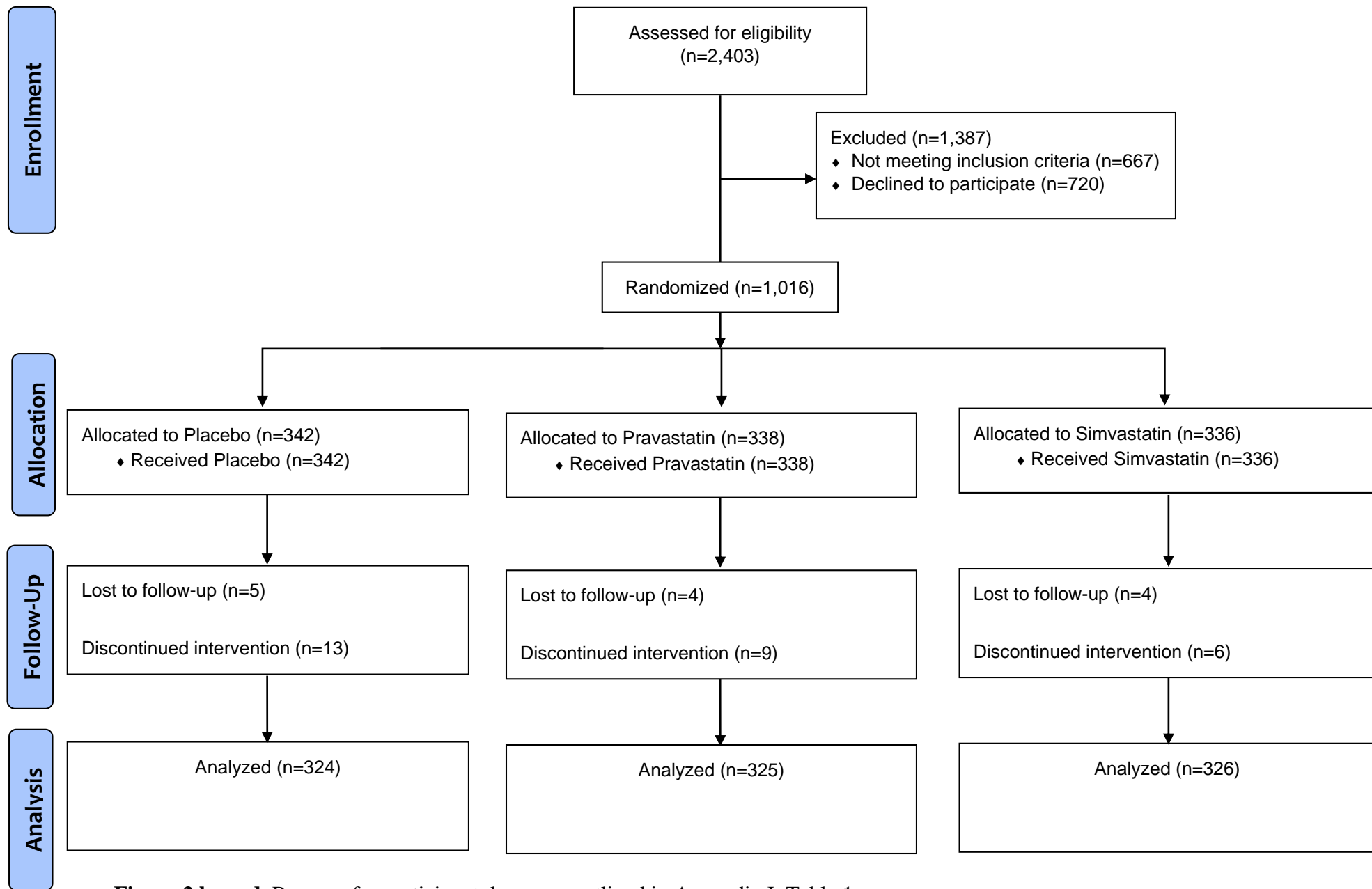


Figure 2 legend. Reasons for participant drops are outlined in Appendix I, Table 1.

Figure 3. Consort Flow Diagram: Men.

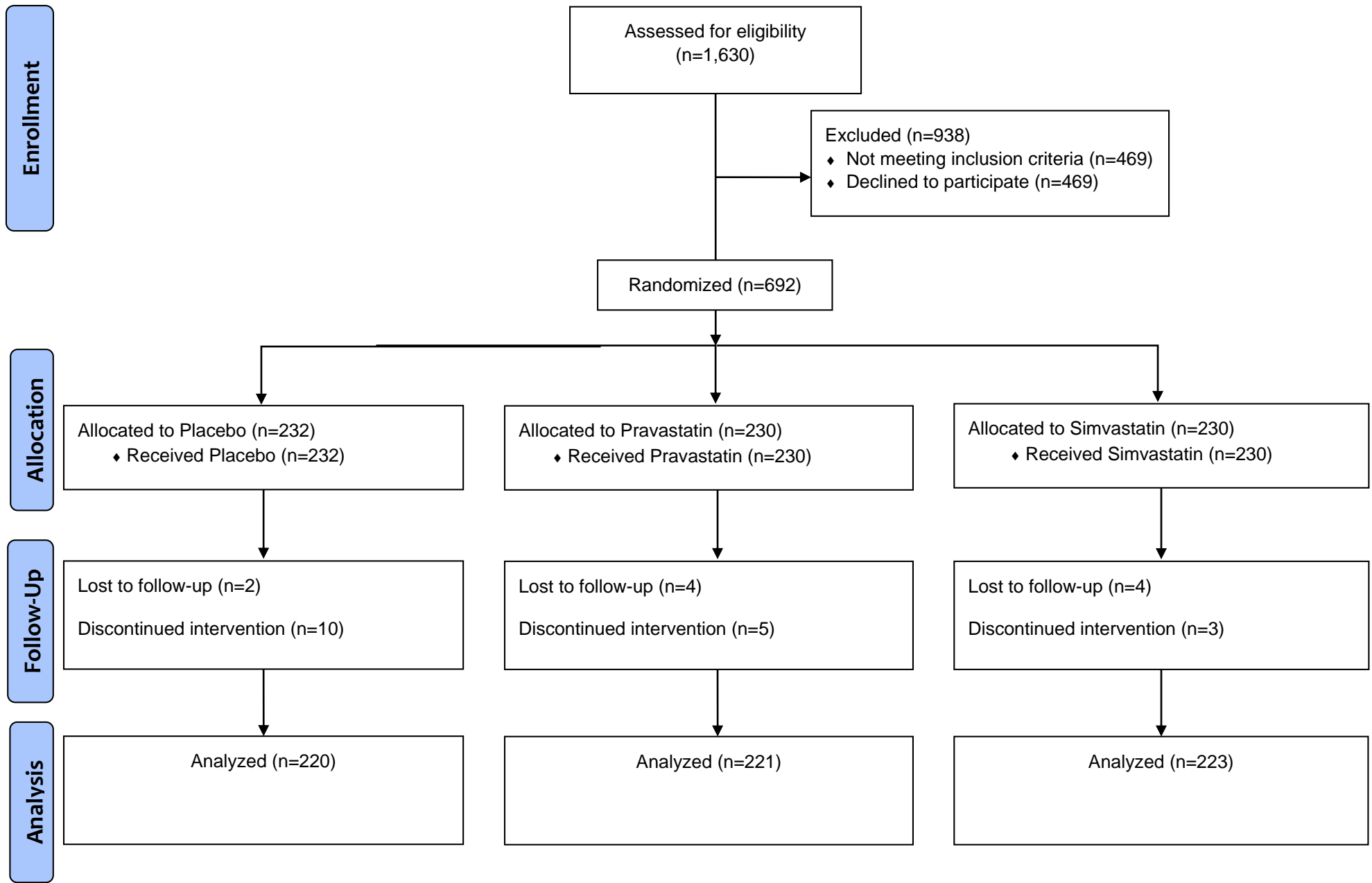


Figure 3 legend. Reasons for participant drops are outlined in Appendix I, Table 1.

Figure 4. Consort Flow Diagram: Women.

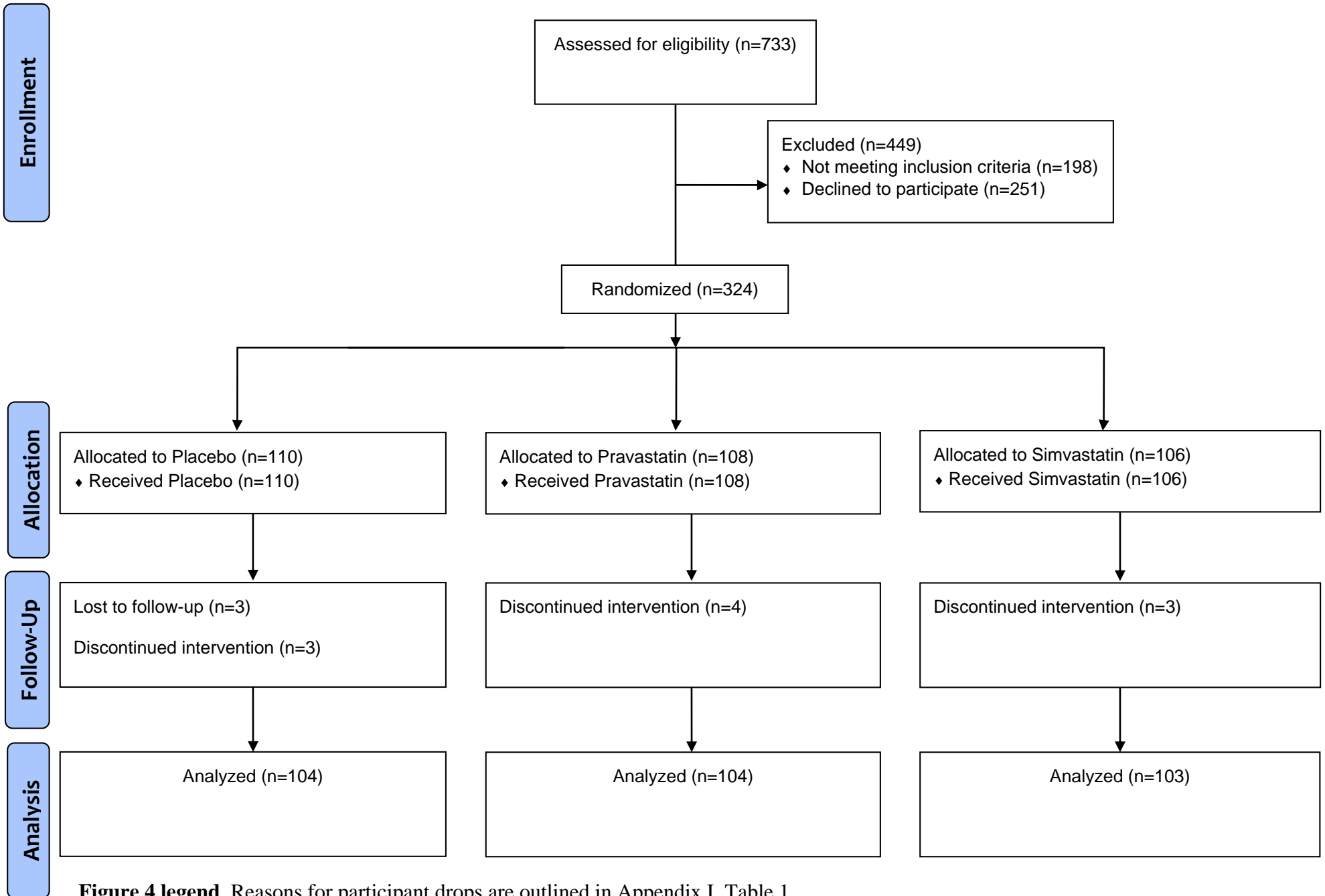


Figure 4 legend. Reasons for participant drops are outlined in Appendix I, Table 1.

Table 1. Reasons for Study Drops.

	Placebo	Pravastatin	Simvastatin
<i>Scheduling</i>	4	1	0
<i>Disliked aspect of study visit</i> (e.g. too far, disliked blood draw, questionnaires, etc)	2	1	0
<i>Physician/PCP recommended they not participate</i>	2	0	2
<i>Surgery</i> (or issues related to medical condition predating participation)	3	1	2
<i>Symptoms</i>	2 a) Felt dizzy b) Felt uneasiness (which dissipated) and some muscular pain	4 a) Irritability, depression, suicidal thoughts and nausea after 10 pills b) Leg pain that subsided following discontinuation c) Muscle pain attributed to study medication d) Upper respiratory infection	1 Muscle pain (also concerned about alcohol plus study medication)
<i>Miscellaneous</i>	0	2 a) Went out of town, forgot to take meds, did not return for f/u b) Due to preexisting tracheostomy, could not take study medications without opening capsules	1 Study psychiatrist felt participation inappropriate (history of depression and suicide attempt)

Table 2. Statin Effects on Lipids.

	All				Men				Women			
	Mean (SD) 95% CI				Mean (SD) 95% CI				Mean (SD) 95% CI			
Completers	N=279	N=558	N=280	N=278	N=193	N=368	N=184	N=184	N=86	N=190	N=96	N=94
	Placebo	Statin	Prava	Simva	Placebo	Statin	Prava	Simva	Placebo	Statin	Prava	Simva
ΔTotal cholesterol, completer	-2.10 (25.8) -92, 86	-51.9 (29.1) -134, 69	-46.6 (28.5) -102, 42	-57.2 (28.7) -134, 69	-3.01 (24.7) -92, 57	-51.1 (27.7) -124, 42	-46.8 (28.9) -102, 42	-55.3 (25.9) -124, 18	-0.058 (28.0) -76, 86	-53.6 (31.5) -134, 69	-46.3 (27.9) -101, 30	-61.0 (33.4) -134, 69
P	-----	<0.0001	<0.0001	<0.0001	-----	<0.0001	<0.0001	<0.0001	-----	<0.0001	<0.0001	<0.0001
ΔLDL, completer	-1.10 (24.0) -84, 67	-44.7 (25.1) -103, 78	-40.4 (24.4) -103, 28	-49.0 (25.1) -102, 78	-1.96 (23.4) -84, 67	-44.4 (23.8) -102, 34	-41.0 (24.2) -95, 28	-47.7 (22.9) -102, 34	0.83 (25.4) -71, 60	-45.4 (27.6) -103, 78	-39.4 (24.9) -103, 27	-51.6 (29.0) -95, 78
P	-----	<0.0001	<0.0001	<0.0001	-----	<0.0001	<0.0001	<0.0001	-----	<0.0001	<0.0001	<0.0001
ΔHDL, completer	-1.80 (8.71) -34, 33	-1.89 (9.69) -37, 47	-1.85 (9.98) -36, 47	-1.94 (9.40) -37, 32	-1.08 (8.51) -34, 33	-1.23 (8.65) -37, 45	-1.74 (8.72) -36, 45	-0.72 (8.58) -37, 32	-3.41 (9.01) -26, 19	-3.16 (11.3) -36, 47	-2.04 (12.1) -36, 47	-4.31 (10.5) -32, 18
P	-----	0.89	0.95	0.86	-----	0.84	0.45	0.69	-----	0.86	0.39	0.54
ΔTrig, completer	-2.09 (58.9) -333, 275	-19.5 (60.5) -623,285	-13.1 (58.3) -266,285	-25.9 (62.0) -623, 181	-2.11 (64.1) -333, 275	-17.6 (61.0) -266, 285	-9.78 (65.4) -266,285	-25.3 (55.2) -192, 181	-2.03 (45.1) -118, 118	-23.2 (59.5) -623, 72	-19.3 (41.0) -151, 67	-27.1 (73.8) -623, 72
P	-----	0.0001	0.027	<0.0001	-----	0.0053	0.25	0.0002	-----	0.0036	0.0073	0.0072
LVCF	N=322	N=645	N=324	N=321	N=219	N=440	N=220	N=220	N=103	N=205	N=104	N=101
ΔTotal cholesterol, LVCF	-1.69 (25.2) -92, 86	-51.2 (28.6) -134, 69	-46.2 (28.0) -102, 42	-56.3 (28.4) -134, 69	-2.43 (24.2) -92, 57	-50.4 (27.4) -124, 42	-46.4 (28.3) -102, 42	-54.4 (25.9) -124, 28	-0.11 (27.4) -76, 86	-53.1 (31.1) -134, 69	-45.8 (27.5) -101, 30	-60.6 (32.9) -134, 69
P	-----	<0.0001	<0.0001	<0.0001	-----	<0.0001	<0.0001	<0.0001	-----	<0.0001	<0.0001	<0.0001
ΔLDL, LVCF	-0.98 (24.0) -84, 67	-44.5 (24.9) -105, 78	-40.2 (24.6) -105, 28	-48.9 (24.6) -102, 78	-1.24 (22.8) -84, 67	-44.1 (23.8) -105, 34	-40.5 (24.6) -105, 28	-47.6 (22.5) -102, 34	-0.44 (26.4) -71, 65	-45.5 (27.2) -103, 78	-39.4 (24.6) -103, 27	-51.8 (28.5) -95, 78
P	-----	<0.0001	<0.0001	<0.0001	-----	<0.0001	<0.0001	<0.0001	-----	<0.0001	<0.0001	<0.0001
ΔHDL, LVCF	-1.51 (8.87) -34, 33	-1.46 (9.60) -37, 47	-1.51 (9.95) -36, 47	-1.40 (9.26) -37, 32	-1.08 (8.74) -34, 33	-0.92 (8.53) -37, 45	-1.56 (8.55) -36, 45	-0.28 (8.48) -37, 32	-2.42 (9.11) -26, 21	-2.60 (11.5) -36, 47	-1.40 (12.5) -36, 47	-3.84 (10.4) - 32, 18
P	-----	0.94	0.99	0.88	-----	0.83	0.56	0.33	-----	0.89	0.50	0.30
ΔTrig, LVCF	-1.84 (58.6) -333, 275	-19.0 (61.3) -623,285	-13.4 (60.1) -266,285	-24.6 (62.0) -623, 181	-2.27 (62.0) -333, 275	-16.9 (62.2) -266, 285	-10.9 (67.3) -266,285	-22.9 (56.0) -192, 181	-0.92 (51.1) -189, 135	-23.5 (59.2) -623, 72	-18.8 (40.5) -151, 67	-28.2 (73.5) -623, 72
P	-----	<0.0001	0.014	<0.0001	-----	0.0046	0.16	0.0003	-----	0.0012	0.0060	0.0024

HDL=high density lipoprotein cholesterol; LDL=low density lipoprotein cholesterol; LVCF=last value carried forward; trig=triglycerides.