

**Table F-10. Harms/adverse effects in studies of other medical interventions**

Harm/Adverse Event*	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
<b>Active tDCS stimulation</b>		
Skin changes <sup>83, 84</sup>	1 (3/10)	30%
<b>Amantadine</b>		
Challenging behavior <sup>91</sup>	1 (2/19)	10%
Insomnia <sup>91</sup>	1 (4/19)	21%
Somnolence <sup>91</sup>	1 (2/19)	10%
<b>Bumetanide</b>		
Hyperactivity <sup>77</sup>	1 (2/27)	7.4%
<b>Buspirone (2.5 mg twice/day)</b>		
Abnormal behavior <sup>99</sup>	1 (5/46)	9%
Affective disorder <sup>99</sup>	1 (8/46)	15%
Agitation/nervousness/restlessness <sup>99</sup>	1 (7/46)	13%
Anxiety <sup>99</sup>	1 (6/46)	11%
Appetite decrease <sup>99</sup>	1 (17/46)	31%
Appetite increase <sup>99</sup>	1 (11/46)	20%
Challenging behavior <sup>99</sup>	1 (33/46)	71.7%
Ear and labyrinth disorders <sup>99</sup>	1 (7/46)	13%
Epistaxis <sup>99</sup>	1 (4/46)	7%
Eye disorders <sup>99</sup>	1 (7/46)	13%
Vomiting <sup>99</sup>	1 (20/46)	37%
Diarrhea <sup>99</sup>	1 (18/46)	33%
Constipation <sup>99</sup>	1 (5/46)	9%
Hyperactivity <sup>99</sup>	1 (15/46)	28%
Immune system disorders <sup>99</sup>	1 (5/46)	9%
Cough <sup>99</sup>	1 (25/46)	46%
Congestion <sup>99</sup>	1 (21/46)	45.6%
Rhinorrhea <sup>99</sup>	1 (15/46)	28%
Pyrexia <sup>99</sup>	1 (31/46)	57%
Ear Infection <sup>99</sup>	1 (11/46)	20%
Upper respiratory tract infection <sup>99</sup>	1 (6/46)	11%
Nasopharyngitis <sup>99</sup>	1 (6/46)	11%
Insomnia <sup>99</sup>	1 (14/46)	30%
Musculoskeletal disorders <sup>99</sup>	1 (5/46)	9%
Skin changes <sup>99</sup>	1 (8/46)	15%
Sleep changes <sup>99</sup>	1 (14/46)	26%
Somnolence <sup>99</sup>	1 (7/46)	13%
Urinary changes <sup>99</sup>	1 (6/46)	11%
<b>Buspirone (5 mg twice/day)</b>		
Abnormal behavior <sup>99</sup>	1 (1/49)	16%
Affective disorder <sup>99</sup>	1 (7/49)	13%
Agitation/nervousness/restlessness <sup>99</sup>	1 (7/49)	13%
Anxiety <sup>99</sup>	1 (3/49)	5%
Appetite decrease <sup>99</sup>	1 (11/49)	20%
Appetite increase <sup>99</sup>	1 (16/49)	29%
Challenging behavior <sup>99</sup>	1 (29/49)	59%
Ear and labyrinth disorders <sup>99</sup>	1 (3/49)	5%
Epistaxis <sup>99</sup>	1 (3/49)	5%
Eye disorders <sup>99</sup>	1 (5/49)	9%
Vomiting <sup>99</sup>	1 (23/49)	42%
Diarrhea <sup>99</sup>	1 (22/49)	40%
Constipation <sup>99</sup>	1 (15/49)	27%
Hyperactivity <sup>99</sup>	1 (12/49)	22%
Immune system disorders <sup>99</sup>	1 (3/49)	5%
Cough <sup>99</sup>	1 (23/49)	42%
Congestion <sup>99</sup>	1 (24/49)	48.9%

Harm/Adverse Event	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
Rhinorrhea <sup>99</sup>	1 (17/49)	31%
Pyrexia <sup>99</sup>	1 (24/49)	44%
Ear Infection <sup>99</sup>	1 (6/49)	11%
Upper respiratory tract infection <sup>99</sup>	1 (3/49)	5%
Nasopharyngitis <sup>99</sup>	1 (4/49)	7%
Insomnia <sup>99</sup>	1 (23/49)	46.9
Musculoskeletal disorders <sup>99</sup>	1 (2/49)	4%
Skin changes <sup>99</sup>	1 (8/49)	15%
Sleep changes <sup>99</sup>	1 (19/49)	35%
Somnolence <sup>99</sup>	1 (6/49)	11%
Urinary changes <sup>99</sup>	1 (7/49)	13%
<b>Divalproex sodium</b>		
Agitation/nervousness/restlessness <sup>75</sup>	1 (2/16)	12.5%
Infection/fever/cold/congestion symptoms <sup>75</sup>	1 (2/16)	12.5%
Insomnia <sup>75</sup>	1 (2/16)	12.5%
Skin changes <sup>75</sup>	1 (2/16)	12.5%
Urinary changes <sup>75</sup>	1 (2/16)	12.5%
<b>Donepezil hydrochloride</b>		
Challenging behavior <sup>90</sup>	1 (5/17)	29.4
<b>Levetiracetam</b>		
Challenging behavior <sup>93</sup>	1 (3/10)	10%-20%
<b>Mecamylamine</b>		
Appetite decrease <sup>88</sup>	1 (4/12)	33.3%
EPS/impaired movement <sup>88</sup>	1 (2/12)	16.7%
GI symptoms <sup>88</sup>	1 (9/12)	75%
Infection/fever/cold/congestion symptoms <sup>88</sup>	1 (9/12)	75%
Mental symptoms <sup>88</sup>	1 (6/12)	50%
Somnolence <sup>88</sup>	1 (5/12)	41.7%
<b>Melatonin</b>		
Appetite decrease <sup>82</sup>	1 (2/6)	35.3%
GI symptoms <sup>82</sup>	1 (4/6)	70.6%
Somnolence <sup>82</sup>	1 (4/6)	70.6%
<b>Memantine</b>		
Affective disorder <sup>97</sup>	1 (2/60)	3.3%
Agitation/nervousness/restlessness <sup>97</sup>	1 (4/60)	6.7%
Challenging behavior <sup>97</sup>	1 (10/60)	8.3%
Enuresis <sup>97</sup>	1 (2/60)	3.3%
GI symptoms <sup>97</sup>	1 (11/60)	1.7%-6.7%
Headache <sup>97</sup>	1 (3/60)	5%
Infection/fever/cold/congestion symptoms <sup>97</sup>	1 (30/60)	1.7%-10%
Insomnia <sup>97</sup>	1 (5/60)	1.7%-6.7%
Self-injurious behavior <sup>97</sup>	1 (2/60)	3.3%
<b>N-acetylcysteine</b>		
Agitation/nervousness/restlessness <sup>89</sup>	1 (3/14)	21.4%
Appetite decrease <sup>89</sup>	1 (2/14)	14.3%
Appetite increase <sup>89</sup>	1 (2/14)	14.3%
Asthma <sup>95</sup>	1 (1/34)	2.9%
Cysts – Unspecified <sup>95</sup>	1 (1/34)	2.9%
EPS/impaired movement <sup>89</sup>	1 (3/14)	21.4%
GI symptoms <sup>89, 95</sup>	2 (23/48)	26.5%100%
Infection/fever/cold/congestion symptoms <sup>89, 95</sup>	2 (20/48)	2.9%-28.6%
Skin changes <sup>95</sup>	1 (2/34)	5.9%

Harm/Adverse Event	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
<b>Tetrahydrobiopterin</b>		
Challenging behavior <sup>86</sup>	1 (4/20)	22%
Hyperactivity <sup>86</sup>	1 (2/20)	9%
Insomnia <sup>86</sup>	1 (2/20)	9%
Skin changes <sup>86</sup>	1 (2/20)	9%
Agitation/nervousness/restlessness <sup>94</sup>	1 (3/5)	60%
Sleeping problems <sup>94</sup>	1 (4/5)	80%
<b>Steroid</b>		
Challenging behavior <sup>92</sup>	1 (10/20)	50%
Cushingoid appearance <sup>92</sup>	1 (18/20)	90%
Hypertension <sup>92</sup>	1 (2/20)	10%
Regression <sup>92</sup>	1 (2/20)	10%
Sleep changes <sup>92</sup>	1 (2/20)	10%
Weight gain <sup>92</sup>	1 (19/20)	95%
<b>Hyperbaric oxygen</b>		
Barotrauma <sup>78</sup>	1 (11/29)	37.9%
<b>Placebo</b>		
Abnormal behavior <sup>97, 99</sup>	2 (11/107)	3.3%-16%
Affective disorder <sup>99</sup>	1 (4/47)	7%
Agitation/nervousness/restlessness <sup>75, 89, 93, 94, 97, 99</sup>	6 (56/117)	1.6%-18%
Anxiety <sup>97, 99</sup>	2 (5/107)	2%-6.6%
Appetite decrease <sup>82, 88, 89, 99</sup>	3 (26/80)	20%-62.5%
Appetite increase <sup>99</sup>	1 (11/47)	19%
Barotrauma <sup>78</sup>	1 (3/29)	10.3%
Challenging behavior <sup>86, 91, 93, 97, 102</sup>	5 (51/148)	4.9%-39%
Epistaxis <sup>97, 99</sup>	2 (9/107)	3.3%-12%
EPS/impaired movement <sup>88, 89</sup>	2 (5/23)	6.7%-25%
GI symptoms <sup>80, 82, 86, 88, 89, 92, 97</sup>	7 (45/141)	1.6%-87.5%
Vomiting <sup>99</sup>	1 (22/47)	39%
Diarrhea <sup>99</sup>	1 (20/47)	35%
Constipation <sup>99</sup>	1 (10/47)	18%
Headache <sup>97</sup>	1 (3/60)	4.9%
Hyperactivity <sup>86, 99</sup>	2 (19/69)	4%-32%
Infection/fever/cold/congestion symptoms <sup>75, 88, 89, 97</sup>	4 (50/94)	1.6%-75%
Insomnia <sup>86, 93</sup>	2 (5/32)	10%-17%
Cough <sup>99</sup>	1 (28/47)	49%
Congestion <sup>99</sup>	1 (27/47)	57.4%
Rhinorrhea <sup>99</sup>	1 (15/47)	26%
Pyrexia <sup>99</sup>	1 (29/47)	51%
Ear Infection <sup>99</sup>	1 (8/47)	14%
Upper respiratory tract infection <sup>99</sup>	1 (12/47)	21%
Nasopharyngitis <sup>99</sup>	1 (6/47)	11%
Insomnia <sup>75, 88, 89, 97, 99</sup>	5 (36/159)	1.8%-34%
Mental symptoms <sup>88</sup>	1 (4/8)	50%
Musculoskeletal disorders <sup>99</sup>	1 (5/47)	9%
Psychomotor hyperactivity <sup>97</sup>	1 (4/60)	6.6%
Repetitive behavior or language <sup>86</sup>	1 (2/22)	9%
Seizure <sup>79, 86</sup>	2 (2/37)	4.5%-6.7%
Skin changes <sup>77, 80, 99</sup>	3 (11/100)	3.7%-12%
Sleep changes <sup>94, 99</sup>	2(18/53)	23%-83%
Somnolence <sup>75, 82, 88, 99</sup>	4 (50/76)	25%-81.3%
Urinary changes <sup>93, 99</sup>	2 (8/57)	10%-12%

\* Harms reported by more than one participant. GI=gastrointestinal; EPS=extrapyramidal